Bijlage 7

Verantwoording

Algemene verantwoording

Tijdens het opstellen van deze richtlijn is een stapsgewijze methode gebruikt om van bewijs naar aanbevelingen te komen. Sommige uitgangsvragen zijn een hernieuwing van de oude richtlijn uit 2010, andere vragen zijn nieuw in deze richtlijn. De methoden die gebruikt zijn, zijn daarom niet helemaal gelijk.

Samenvatten literatuur

Voor de uitgangsvragen waar nieuwe literatuur is gezocht, is gebruikgemaakt van een systematische aanpak. Deze aanpak en de resultaten daarvan staan hieronder beschreven voor de uitgangsvragen.

Vaststellen kwaliteit van bewijs

Voor individuele artikelen over screeningsinstrumenten is de Quality Assessment of Diagnostic Accuracy Studies-2 gebruikt (QUADAS-2)[19], wat ook de voorkeurstool is bij een aanpak volgens Grading of Recommendations, Assessment, Development, and Evaluations (GRADE)[20]. De uitgangsvragen met betrekking tot interventies gebruiken de Joanna Briggs Institute (JBI) checklists die passen bij de studie designs. De gevonden systematische literatuuronderzoeken werden beoordeeld met de Assessing the Methodological Quality of Systematic Reviews 2 (AMSTAR-2) checklist. Resultaten van de beoordelingen staan in onderstaande beschrijving bij de uitgangsvragen.

Opstellen Overwegingen en Aanbevelingen (evidence to decision framework)

Vanwege de lage mate van bewijs en het geringe aantal studies bij de meeste uitgangsvragen zijn aanbevelingen opgesteld die zijn gebaseerd op de gevonden literatuur, bestaande richtlijnen en expertmeningen van de werkgroep. Bestaande richtlijnen waarnaar in de overwegingen gerefereerd wordt, zijn niet altijd gebaseerd op literatuur en niet altijd specifiek opgesteld voor verzorgenden, verpleegkundigen en verpleegkundig specialisten, maar worden door de werkgroep als acceptabel beschouwd

Nadat de literatuur per uitgangsvraag was verzameld, is een vergadering met de werkgroep gehouden waarin twee patient journeys centraal stonden. Deze waren niet specifiek gericht op een uitgangsvraag. Alle stappen van de zorg werden besproken. Vooral ook de organisatie van zorg kwam hier ter sprake. Zie hieronder voor de twee persona die gebruikt zijn tijdens de discussie. Het doel van deze bijeenkomst was om de gevonden literatuur in perspectief te plaatsen, en uit te zoeken welke elementen van de zorg niet met een zoekactie in de literatuur zijn gevonden, maar wel beschreven dienen te worden.

---

[19] Whiting PF, Rutjes AW, Westwood ME, Mallett S, Deeks JJ, Reitsma JB, Leeflang MM, Sterne JA, Bossuyt PM; QUADAS-2 Group. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med. 2011 Oct 18;155(8):529-36.

[20] Schünemann, H. J., Oxman, A. D., Brozek, J., Glasziou, P., Jaeschke, R., Vist, G. E., ... & Guyatt, G. H. (2008). Grading quality of evidence and strength of recommendations for diagnostic tests and strategies. Bmj, 336(7653), 1106-1110.

Met de werkgroep is besproken welke zorg de fictieve cliënten zouden moeten ontvangen in een ideale situatie. Opvallend was daarbij dat schaamte en taboes veel werden besproken, terwijl deze in de literatuur weinig naar voren kwamen als onderwerpen. Vanuit de literatuur is vooral informatie gevonden over instrumenten die (de ernst) continentie vaststellen, maar is minder aandacht voor wensen en behoefte van cliënten. Bij de uitgangsvragen over diagnostiek en interventies is daarom besloten in de aanbevelingen en overwegingen meer aandacht te besteden aan wensen en behoefte van cliënten.

Naast het overleg met de patient journeys, is er schriftelijk input gevraagd aan de werkgroepleden. Dit is gedaan door de tekst voor elke uitgangsvraag afzonderlijk voor te leggen. Voor elke uitgangsvraag is een tabel opgesteld met daarin de voorgestelde aanbevelingen op een rij. Voor de hernieuwde uitgangsvragen werd aangegeven of werd afgeweken van de oude richtlijn en waarom. Vooral bij de interventies is de volgorde van de aanbevelingen relevant omdat niet elke interventie even belastend is voor de cliënt, daarom is er ook in de werkgroepoverleggen gediscussieerd over de juiste volgorde. Bij voorkeur wordt een balans gevonden tussen effectiviteit en kans op nadelige gevolgen voor de cliënt (bijvoorbeeld bijwerkingen of tijdsinspanning).

In de tabel werden de volgende algemene vragen gesteld om rekening mee te houden bij het opstellen van de nieuwe aanbevelingen:

1. Welk beleid is geschikt?
2. Op welk moment is het beleid aan de orde?
3. Bij welke cliëntengroep?
4. Kan de aanbeveling door elke verpleegkundige en verzorgende worden uitgevoerd, of is er onderscheid nodig?
5. Hoe voer je het beleid uit, wat moet je dan doen?
6. Is er een specifieke plaats waar je het beleid uitvoert?
7. Waarom voer je het beleid uit, tot welke verbeterde uitkomstmaten leidt het beleid?

Per voorgestelde aanbeveling werden soms nog extra vragen aan de werkgroep voorgelegd. Bijvoorbeeld bij twijfel of een bepaald instrument of interventie in de Nederlandse wijkverpleging wel wordt toegepast. Voor sommige aanbevelingen is de bewijslast uit de literatuur erg minimaal. Er is dan gevraagd aan de werkgroep hoe sterk ze de aanbeveling wilden maken. Als de aanbeveling met weinig bewijs toch als belangrijk werd beschouwd, moest daar argumentatie voor worden gegeven zodat die in de overwegingen meegenomen kon worden.

De werkgroepleden reageerden individueel op de vragen. De ontwikkelaar heeft daarna een nieuwe versie van de tabel gemaakt met daarin een nieuwe kolom voor de aangepaste aanbevelingen. Voor de transparantie was ook het commentaar op de vorige ronde zichtbaar. Deze nieuwe tabellen zijn opnieuw naar de werkgroep verstuurd. De aanbevelingen waar nog geen consensus over was bereikt of waar niet voldoende onderbouwing voor was, zijn in een bijeenkomst opnieuw besproken.

Kennislacunes

Aan de hand van het literatuuronderzoek (peer-reviewed artikelen en richtlijnen) zijn de kennislacunes bepaald door de projectgroep. Daarna zijn ze besproken met de werkgroep. Zie bijlage 10 voor de kennislacunes

Commentaarfase

Het doel van de commentaarfase was om de aanbevelingen in de conceptrichtlijn te toetsen op inhoud. Op basis van het ontvangen commentaar zijn er aanpassingen gedaan aan de richtlijntekst. Aan de partijen die uitgenodigd werden werd gevraagd of ze de richtlijn kritisch konden lezen en becommentariëren met specifiek aandacht voor:

- Feitelijke onjuistheden of ontbrekende informatie

- De begrijpelijkheid/concreetheid van de aanbevelingen
- De complexiteit van de aanbevelingen of richtlijntekst
- Helderheid van de formuleringen
- De relevantie van de aanbevelingen voor de zorgvrager(s)

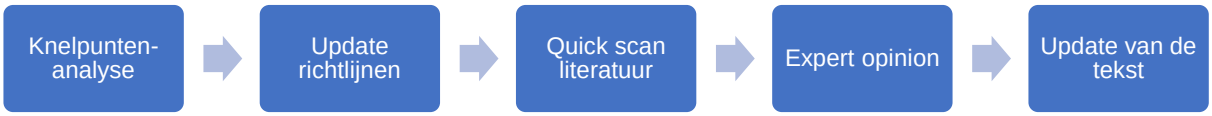
De ontvangen commentaar zijn vervolgens in één document verzameld en gerangschikt op paginanummer of module. De commentaren en mogelijke aanpassingen zijn vervolgens in een werkgroep vergadering besproken.

De wijzigingen die naar aanleiding van de commentaarfase zijn gemaakt zijn samengevat in de verantwoording per module. Zie Bijlage 2 voor de organisaties die de richtlijn van commentaar hebben voorzien.

Verantwoording per module

Verantwoording Uitgangsvraag 1 – Diagnostiek bij urine-incontinentie

De knelpuntenanalyse vormde de basis van de methodiek die gebruikt zou worden bij het updaten van de uitgangsvraag. De tekst van uitgangsvraag 1- Diagnostiek UI is geüpdatet door middel van het beoordelen van de updates van de internationale richtlijnen die in de oude richtlijn werden gebruikt, en een quick scan van literatuur. Daarnaast was expert opinion van de werkgroep belangrijk omdat recent wetenschappelijk bewijs voor de Nederlandse situatie in de wijkverpleging bij ouderen nagenoeg ontbreekt. In onderstaande paragrafen is stap-voor-stap uitgelegd hoe de update van uitgangsvraag 1 is uitgevoerd.



Figuur 1. Schematische weergave van de methodiek

Van knelpuntenanalyse naar richtlijnontwikkeltraject

De aanbevelingen in de oude richtlijn zijn voornamelijk gebaseerd op andere richtlijnen. Een aantal daarvan heeft inmiddels een update gehad (bijvoorbeeld NICE 2006 > 2019). De richtlijnen waren destijds niet heel specifiek gericht op kwetsbare ouderen en het is niet aannemelijk dat dat nu wel het geval is, aangezien de literatuurupdate in de knelpuntenanalyse weinig nieuw wetenschappelijk bewijs opleverde specifiek over kwetsbare ouderen.

Tijdens de knelpuntenanalyse was de werkgroep destijds van mening dat de aanbevelingen in de richtlijn nog steeds accuraat zijn, en dat gebrek aan kennis en kunde bij professionals het grootste knelpunt is bij het volgen van de richtlijn op dit punt. Er werd geadviseerd om een werkgroep bestaande uit ervaren professionals nogmaals naar de tekst van de oude richtlijn te kijken en deze te verduidelijken en vereenvoudigen waar nodig. Vervolgens moet worden zorggedragen dat dit ook daadwerkelijk bij de professionals bekend wordt (implementatie). In een later stadium kan dan opnieuw geëvalueerd worden of er in de praktijkproblemen worden ervaren met het uitvoeren van de aanbevelingen.

Update Richtlijnen

De tekst en aanbevelingen uit de oude richtlijn zijn gebaseerd op internationale richtlijnen. Er is gekeken welke van deze richtlijn een update hebben gehad, en of nieuwe internationale richtlijnen zijn uitgekomen van beroepsverenigingen na het verschijnen van de oude richtlijn. Hieronder worden de richtlijn weergegeven, en daarbij de kwaliteitsbeoordeling met behulp van de AGREE II-Global Rating Scale (AGREE II-GRS) Instrument[21].

Bestudering van de aanbevelingen in de nieuwste internationale richtlijnen laat zien dat de aanbevelingen nauwelijks zijn aangepast. Bijvoorbeeld in de NICE richtlijn uit 2019 staan 21 aanbevelingen die betrekking hebben op het vaststellen van UI. Van deze 21 zijn er vijf aanbevelingen aangepast (amended) en twee volledig nieuw (Urodynamic testing).

Hieronder worden de richtlijnen weergegeven die in de oude richtlijntekst worden gebruikt (Tabel 9), daarna nieuwe relevante richtlijnen (Tabel 10), en vervolgens de kwaliteitsbeoordeling met AGREE II-GRS van de nieuwe richtlijnen (Tabel 11).

Tabel 9. Oude richtlijnen in module diagnostiek in richtlijn 2010.

Richtlijn in 2010		Update beschikbaar?	AGREE Score*
Scottish intercollegiate guideline network (SIGN) (2004)	Management of urinary incontinence in primary care	Geen update	67
MOH nursing clinical practice guidelines (2003)	Nursing management of patients with urinary incontinence	Geen update	74
The National Institute for Health and Care Excellence (NICE) (2006)	Urinary incontinence, the management of urinary incontinence in women	NICE-2019: https://www.nice.org.uk/guidance/ng123	90
Boek: ICS-2005	Urinary Incontinence	ICS-2017. Binnenkort ook 2023, nu nog geen toegang tot	nvt

** beoordeeld door opstellers richtlijn 2010*

Tabel 10. Nieuwe richtlijnen voor diagnostiek sinds verschijnen oude V&VN richtlijn.

Auteur (jaar)	Titel	Literature based of expert opinion?
The National Institute for Health and Care Excellence (NICE) (2019)	Urinary incontinence, the management of urinary incontinence in women	Combinatie

[21] https://www.agreetrust.org/wp-content/uploads/2013/12/AGREE-II-GRS-Instument.pdf

European Association of Urology (EAU) (2020)	Urinary Incontinence in Adults	Combinatie
Federatie medisch specialisten (FMS) (2014)	Urine-incontinentie (UI) 2e- en 3e-lijnszorg	Combinatie

Tabel 11. Beoordeling nieuwe richtlijnen met AGREE II-GRS score (1= lowest quality; 7= highest quality).

NICE (2019): Urinary incontinence and pelvic organ prolapse in women: management		
Item	Description	Score
1. Rate the overall quality of the guideline Development methods	Consider: Were the appropriate stakeholders involved in the development of the guideline? Was the evidentiary base developed systematically? Were recommendations consistent with the literature?	6
2. Rate the overall quality of the guideline presentation	Consider: Was the guideline well organized? Were the recommendations easy to find?	6
3. Rate the completeness of reporting.	Consider: Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?	6
4. Rate the overall quality of the guideline recommendations	Consider: Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?	6
Rate the overall quality of the guideline.		6

EAU (2020): Urinary incontinence in adults		
Item	Description	Score
1. Rate the overall quality of the guideline Development methods	Consider: Were the appropriate stakeholders involved in the development of the guideline? Was the evidentiary base developed systematically? Were recommendations consistent with the literature?	6
2. Rate the overall quality of the guideline presentation	Consider: Was the guideline well organized? Were the recommendations easy to find?	5
3. Rate the completeness of reporting.	Consider: Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?	5
4. Rate the overall quality of the guideline recommendations	Consider: Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?	6
Rate the overall quality of the guideline.		5

FMS (2014): Urine-incontinentie (UI) 2e- en 3e-lijnszorg		
Item	Description	Score
1. Rate the overall quality of the guideline Development methods	Consider: Were the appropriate stakeholders involved in the development of the guideline? Was the evidentiary base developed systematically? Were recommendations consistent with the literature?	6
2. Rate the overall quality of the guideline presentation	Consider: Was the guideline well organized? Were the recommendations easy to find?	6
3. Rate the completeness of reporting.	Consider: Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?	6
4. Rate the overall quality of the guideline recommendations	Consider: Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?	6
Rate the overall quality of the guideline.		6

Quick scan literatuur

De nieuwste richtlijnen zijn uit 2019 en 2020. De aanbevelingen in de geüpdatete richtlijnen zijn weinig veranderd ten opzichte van eerdere versies. Ook blijft een deel van de aanbevelingen expert-opinion. Samen met de conclusie uit de knelpuntenanalyse bevestigt dit het vermoeden dat er weinig recent wetenschappelijk bewijs is dat de aanbevelingen van richting zal doen veranderen.

Met een beknopte zoekactie is opnieuw gezocht in de literatuur om dit nogmaals te bevestigen en te kijken of er sinds de nieuwste internationale richtlijnen nieuw bewijs is gepubliceerd. Dit literatuuronderzoek is uitgevoerd in het jaar 2023 (d.d: 11-07-2023). Er is gezocht in Medline (via Pubmed).

Volgens de AQUA-leidraad[22] is elke uitgangsvraag vertaald in een PICO vraag, die het probleem of patiënt/populatie (P), de interventie (I), de vergelijking (comparison, C) en de gewenste uitkomstmaat (outcome, O) beschrijven. In Tabel 12 staat de PICO-vraag uitgewerkt voor uitgangsvraag 1.

Tabel 12. PICO bij uitgangsvraag diagnostiek bij urine-incontinentie.

P:	Ouderen met urine-incontinentie, gemiddelde leeftijd in populatie ≥60 j
I:	Diagnostische instrumenten voor urine-incontinentie: - Anamnese - Urinekweek - Padtest, 3IQ test - Vragenlijsten inventarisatie lichamelijke en cognitieve beperkingen - Residubepaling - Vragenlijst symptoomscores (ICIQ, OAB-q, UDI, LUTS, BFLUTS, PRAFAB) - Mictiedagboek - Deficatiedagboek

[22] https://www.zorginzicht.nl/ontwikkeltools/ontwikkelen/aqua-leidraad

C:	Ander meetinstrument dat hierboven genoemd wordt voor urine-incontinentie
O:	Betrouwbaarheid/ validiteit/ toepasbaarheid/ herhaalbaarheid

De PICO-vraag is omgezet in zoektermen die gecombineerd zijn tot een zoekstrategie waarmee de gewenste literatuur geïdentificeerd is (Tabel 13).

Tabel 13. Zoekstrategie Pubmed.

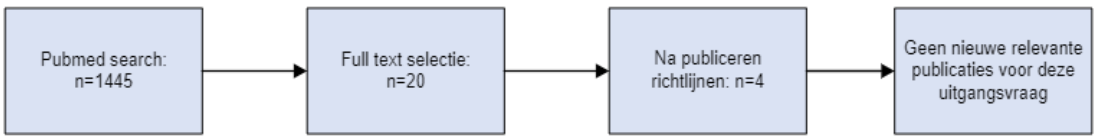
Onderwerp	
#1: Incontinentie	urinary incontinence[Mesh] OR urinary incontinence[tiab] OR "urine incontinence"[tiab]
#2: Studie populatie	"Frail Elderly"[Mesh] OR "Aged, 80 and over"[Mesh] OR frail*[tiab] OR elder*[tiab] OR geriatric*[tiab]
# 3: Focus van de studies: diagnostiek	"diagnosis"[Mesh] OR "diagnosis"[Subheading] OR "diagnos*"[tiab]
#4: Publicatietype	randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled[tiab] OR placebo*[tiab] OR trial[tiab] OR intervention[tiab] OR "Cross-Over Studies"[Mesh] OR "Double-Blind Method"[Mesh] OR "Prospective Studies"[Mesh] OR "Follow-up Studies"[Mesh] OR "Cohort Studies"[Mesh] OR crossover[tiab] OR cross-over[tiab] OR double-blind[tiab] OR doubleblind[tiab] OR single-blind[tiab] OR singleblind[tiab] OR cohort*[tiab] OR prospective[tiab] OR longitudinal[tiab] OR observational[tiab] OR follow-up[tiab] OR followup[tiab] OR effectiveness[tiab] OR safety[tiab]
Limits	Publication date 01/01/2008 – 11/07/2023
#1 AND #2 AND #3 AND #4 + limits	

Voor de selectie van relevante artikelen zijn in- en exclusiecriteria geformuleerd. De volgende in- en exclusiecriteria zijn vastgesteld:

Tabel 14. In- en exclusiecriteria.

	Inclusie	Exclusie
Publicatieperiode	/	/
Scope	Wereldwijd	/
Taal	Engels, Nederlands	Overige talen
Studiepopulatie	Ouderen, Gemiddelde leeftijd in onderzoekspopulatie ≥60 jaar	- Zwangere vrouwen - Vrouwen tijdens en voor de menopauze - Kinderen, adolescenten - Dierstudies - Mensen die al langer incontinentie zijn door een degeneratieve ziekte (MS, ALS) - Mensen met een verstandelijke beperking

	Verpleegkundigen en verzorgenden werkzaam in de wijk	Professionals niet werkzaam in de wijk
Focus van de studie	Diagnostiek van urine-incontinentie: - Anamnese - Mictiedagboek - deficatiedagboek - Urinekweek - Padtest - Vragenlijsten inventarisatie lichamelijke en cognitieve beperkingen - Residubepaling - Vragenlijst symptoomscores (ICIQ, OAB-q, UDI, LUTS, BFLUTS, PRAFAB)	- Chirurgische ingrepen - Preventie - Interventies
Studie uitkomsten	Validiteit Betrouwbaarheid Herhaalbaarheid Toepasbaarheid	
Studieresultaten	Nieuwe methoden of nieuwe resultaten	Herhaling van wat bekend is uit oudere onderzoeken
Publicatietype	Peer-reviewed artikelen	- Boek - Letter to the editor - Commentaar - Editorial - Congres abstract
Studiedesign	- Gerandomiseerde gecontroleerde studies (RCT) - Observationele studies	- Case report - Case series - Narratieve reviews - Literatuur review/ Meta-analyse



Figuur 2. Schematische weergave selectieproces quick scan literatuur.

De artikelen die op basis van titel en abstract zijn geïncludeerd (n=20) zijn vervolgens opgesplitst in 16 artikelen die zijn gepubliceerd vóór en vier na de laatste revisie van de EAU richtlijn.

Van de vier artikelen die na de laatste revisie van de EAU richtlijn zijn gepubliceerd is bekeken of zij een nieuwe diagnostische instrumenten beschrijven ten opzichte van de oude V&VN richtlijn. Daarnaast is gekeken of de beschreven instrumenten in de nieuwste internationale richtlijnen voorkomen.

Als zij bestaande diagnostische instrumenten beschreven is gekeken of de conclusie afwijkt van de internationale richtlijnen. Als dit niet het geval was dan geldt de internationale richtlijn als hoger bewijs en is de conclusie uit de richtlijn overgenomen. Daarnaast beschrijft de oude richtlijn dat er gebrek is aan bewijs dat internationale instrumenten goed werken in de Nederlandse situatie. De richtlijnmakers concludeerden destijds: "*Er is onderzoek gewenst om Nederlandse vertalingen van internationale vragenlijsten kwaliteit van leven en/of symptoomscores (o.a. de I-QOL en de SEAPI-QMM en de KHQ) te valideren voor gebruik bij ouderen in de Nederlandse praktijk*." Een vragenlijst waar de werkgroep destijds wel goede ervaring mee had was de PRAFAB (Hendriks et al., 2008).

Bij nieuwe diagnostische instrumenten is gekeken of deze relevant zijn voor de Nederlandse situatie in de wijkverpleging en bij ouderen.

Uiteindelijk zijn er geen aanvullende relevante wetenschappelijke artikelen gevonden.

Tabel 15. Artikelen geïncludeerd na selectie van titel en abstract (n=20).

Pub jaar	Referentie	Opmerking *Uit abstract referentie*	Nieuwe tool of methode of specifiek voor situatie NL Ja/nee
2008	Naoemova, I., S. De Wachter, F. L. Wuyts and J. J. Wyndaele (2008). "Reliability of the 24-h sensation-related bladder diary in women with urinary incontinence." Int Urogynecol J Pelvic Floor Dysfunct **19**(7): 955-959.	Niet na richtlijnen verschenen	nee
2008	Piault, E., C. J. Evans, D. Espindle, Z. Kopp, L. Brubaker and P. Abrams (2008). "Development and validation of the Overactive Bladder Satisfaction (OAB-S) Questionnaire." Neurourol Urodyn **27**(3): 179-190.	*Idem*	nee
2009	Tannenbaum, C., J. Brouillette, J. Michaud, N. Korner-Bitensky, C. Dumoulin, J. Corcos, M. Tu le, M. C. Lemieux, S. Ouellet and L. Valiquette (2009). "Responsiveness and clinical utility of the geriatric self-efficacy index for urinary incontinence." J Am Geriatr Soc **57**(3): 470-475.	*Idem*	nee
2009	Twiss, C., V. Triaca, J. Anger, M. Patel, A. Smith, J. H. Kim, S. Raz and L. V. Rodríguez (2009). "Validating the incontinence symptom severity index: a self-assessment instrument for voiding symptom severity in women." J Urol **182**(5): 2384-2391.	*Idem*	nee
2012	Basra, R. K., E. Cortes, V. Khullar and C. Kelleher (2012). "A comparison study of two lower urinary tract symptoms screening tools in clinical practice: the B-SAQ and OAB-V8 questionnaires." J Obstet Gynaecol **32**(7): 666-671.	*Idem*	nee
2012	Li, B., L. Zhu, T. Xu and J. Lang (2012). "The optimal threshold values for the severity of urinary incontinence based on the 1-hour pad test." Int J Gynaecol Obstet **118**(2): 117-119.	*Idem*	nee
2013	Hsiao, S. M., H. H. Lin and H. C. Kuo (2013). "International Prostate Symptom Score for assessing lower urinary tract dysfunction in women." Int Urogynecol J **24**(2): 263-267.	*Idem*	nee
2013	Patrick, D. L., K. M. Khalaf, R. Dmochowski, J. W. Kowalski and D. R. Globe (2013). "Psychometric performance of the incontinence quality-of-life	*idem*	nee

Pub jaar	Referentie	Opmerking *Uit abstract referentie*	Nieuwe tool of methode of specifiek voor situatie NL Ja/nee
	questionnaire among patients with overactive bladder and urinary incontinence." Clin Ther **35**(6): 836-845.		
2013	Tsui, J. F., M. B. Shah, J. M. Weinberger, M. Ghanaat, J. P. Weiss, R. S. Purohit and J. G. Blaivas (2013). "Pad count is a poor measure of the severity of urinary incontinence." J Urol **190**(5): 1787-1790.	*idem*	nee
2014	Marotte, J. B., B. Johnson, D. M. Johnson and J. O. Sams (2014). "Using the 3 incontinent questions (3IQ) to distinguish between urge urinary incontinence (UUI) and stress urinary incontinence (SUI) in the practitioner adult female population." J Ark Med Soc **110**(8): 164-165.	*idem*	nee
2014	Sahai, A., C. Dowson, E. Cortes, J. Seth, J. Watkins, M. S. Khan, P. Dasgupta, L. Cardozo, C. Chapple, D. De Ridder, A. Wagg and C. Kelleher (2014). "Validation of the bladder control self-assessment questionnaire (B-SAQ) in men." BJU Int **113**(5): 783-788.	*idem*	nee
2014	Suskind, A. M., R. L. Dunn, D. M. Morgan, J. O. DeLancey, E. J. McGuire and J. T. Wei (2014). "The Michigan Incontinence Symptom Index (M-ISI): a clinical measure for type, severity, and bother related to urinary incontinence." Neurourol Urodyn **33**(7): 1128-1134.	*idem*	nee
2016	Hikita, K. S., M. Honda, S. Hirano, B. Kawamoto, T. Panagiota, K. Muraoka, T. Sejima and A. Takenaka (2016). "Comparison of the overactive bladder symptom score and the overactive bladder symptom score derived from the bladder diaries." Neurourol Urodyn **35**(3): 349-353.	*idem*	nee
2016	Krhut, J., M. Gärtner, K. Zvarová, M. Desarno and P. Zvara (2016). "Validating of a Novel Method for Electronically Recording Overactive Bladder Symptoms in Men." Low Urin Tract Symptoms **8**(3): 177-181.	*idem*	nee
2016	Timmermans, L., F. Falez, C. Melot, S. Higuet and D. Vincent (2016). "Use of the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) for an objective assessment of disability determination according to the Modified Katz Scale: a prospective longitudinal study." Minerva Urol Nefrol **68**(4): 317-323.	*idem*	nee

Pub jaar	Referentie	Opmerking *Uit abstract referentie*	Nieuwe tool of methode of specifiek voor situatie NL Ja/nee
2017	Elmer, C., A. Murphy, J. O. Elliott and N. M. Book (2017). "Twenty-Four-Hour Voiding Diaries Versus 3-Day Voiding Diaries: A Clinical Comparison." Female Pelvic Med Reconstr Surg **23**(6): 429-432.	*idem*	nee
2019	Sacco, E., R. Bientinesi, C. Gandi, L. Di Gianfrancesco, F. Pierconti, M. Racioppi and P. Bassi (2019). "Patient pad count is a poor measure of urinary incontinence compared with 48-h pad test: results of a large-scale multicentre study." BJU Int **123**(5a): E69-e78.	pad count *pad count should not be used instead of the pad test as an objective measure of UI when an accurate evaluation is required for research or clinical purposes.*	Nee Werd al niet geadviseerd om te gebruiken in oude richtlijn.
2021	Skorupska, K., M. E. Grzybowska, A. Kubik-Komar, T. Rechberger and P. Miotla (2021). "Identification of the Urogenital Distress Inventory-6 and the Incontinence Impact Questionnaire-7 cutoff scores in urinary incontinent women." Health Qual Life Outcomes **19**(1): 87.	Urogenital Distress Inventory-6 and the Incontinence Impact Questionnaire-7 cutoff scores	Nee Bestaande tools, conclusie wijkt niet af van internationale richtlijnen
2021	Sussman, R. D., C. Escobar, D. Jericevic, C. Oh, A. Arslan, R. Palmerola, D. M. Pape, S. W. Smilen, V. W. Nitti, N. Rosenblum and B. M. Brucker (2021). "Estimation of Urinary Frequency: Does Question Phrasing Matter?" Urology **156**: 90-95.	Question Phrasing Matter *When compared to a voiding diary for daytime urinary frequency, asking patients how many times they urinated underestimated, and asking patients how many hours they waited between urinations overestimated the number recorded voids. Regardless of phrasing, patients overestimated nighttime urination. Patients in our functional urology population have limited numeracy, which may impact accuracy of urinary frequency estimation.*	Nee Niet relevant in Nederlandse situatie met wijkverpleging
2022	Reddy, M., S. Kusin, A. Christie and P. Zimmern (2022). "A Deception Study to Avoid Recall Bias Confirms Similar Scores for 3 Validated Questionnaires in the Office or Over the Phone in	*The 3 questionnaire scores were overall comparable when obtained over the phone or during office visits.*	Nee

Pub jaar	Referentie	Opmerking *Uit abstract referentie*	Nieuwe tool of methode of specifiek voor situatie NL Ja/nee
	Women With or Without Urinary Incontinence." J Urol **208**(6): 1288-1294.	*Women with incontinence, who may otherwise be lost to follow-up or only reachable by telehealth calls, can benefit from the remote administration of these 3 questionnaires.*	Niet relevant in Nederlandse situatie met wijkverpleging

Expert opinion

Een belangrijk deel van de aanbevelingen kan niet op literatuur gebaseerd worden omdat weinig relevante wetenschappelijke literatuur beschikbaar is voor de Nederlandse situatie in de wijkverpleging en specifiek voor (kwetsbare) ouderen. Met de werkgroep is gediscussieerd over goede incontinentiezorg tijdens vergaderingen en in schriftelijke rondes. Tijdens deze discussies is expliciet besproken of de aanbevelingen en overwegingen uit internationale richtlijnen ook toepasbaar zijn in de Nederlandse setting. Daarbij werd ook rekening gehouden met de doelgroep ouderen en of het toepasbaar is bij zowel mannen als vrouwen.

Bij het thema diagnostiek is ook aan de werkgroep gevraagd om samenhang te zoeken tussen diagnostiek bij urine én fecale incontinentie, zodat de twee modules goed op elkaar aansluiten.

Update tekst

De tekst van de oude richtlijn is opgesteld in 2008 en behoefde een update in stijl en opmaak. De tekst is omgezet naar het nieuwe V&VN template voor richtlijnen. Waarbij koppen zijn aangepast en tekst ingekort, waar nodig.

Daarnaast zijn de aanbevelingen uit de geüpdatete internationale richtlijnen toegevoegd. Aangezien de internationale richtlijnen relatief weinig veranderingen hebben ondergaan is er gekozen om de oude richtlijntekst over te nemen en alleen daar waar grote wijzigingen zijn de tekst aan te passen. De overwegingen zijn aangevuld of aangepast waar nodig.

Bij elke werkgroep vergadering was minstens één patiëntvertegenwoordiger aanwezig. In de nieuwe richtlijntekst is meer aandacht voor wensen en behoeften van patiënten en voor samenwerking met andere disciplines en mantelzorgers. Door hier meer aandacht aan te besteden hoopt de werkgroep dat de richtlijn meer aansluit bij de huidige tijd.

Commentaarfase en aanpassingen

Naar aanleiding van de commentaarfase zijn de volgende punten aangepast:

- Er is een aanbeveling toegevoegd over schaamtegevoelens. Deze aanbeveling stond wel al bij fecale incontinentie.
- Enkele tekstuele wijzigingen zijn gemaakt in de aanbevelingen en de moduletekst ten behoeve van de leesbaarheid, zoals het uitschrijven van UI als urine-incontinentie in de aanbevelingen.
- De aanbevelingen over de vragenlijsten zijn uitgebreid met een kleine tabel met het doel van elke vragenlijst.

Verantwoording Uitgangsvraag 2- Diagnostiek voor fecale incontinentie

Literatuursearch en selectie

Systematisch literatuuronderzoek is uitgevoerd in het jaar 2023 (d.d: 10-02-2023). Er is gezocht in drie databases: Medline (via Pubmed), Embase en Cinahl.

Volgens de AQUA-leidraad is elke uitgangsvraag vertaald in een PICO vraag, die het probleem of patiënt/populatie (P), de interventie (I), de vergelijking (comparison, C) en de gewenste uitkomstmaat (outcome, O) beschrijven. In Tabel 16 staat de PICO-vraag uitgewerkt voor uitgangsvraag 2.

Tabel 16. PICO bij uitgangsvraag diagnostiek bij fecale incontinentie.

P:	Ouderen, gemiddelde leeftijd in populatie ≥60 j
I:	Diagnostische instrumenten voor fecale incontinentie: - Anamnese - Anaal functieonderzoek - Defecatiedagboek - Mictiedagboek - Vragenlijst symptoomscores (Wexner score; fecal incontinence quality of life questionnaire; Vaizey score; fecal incontinence severity index) - Vragenlijst kwaliteit van leven
C:	Ander meetinstrument dat hierboven genoemd wordt voor fecale incontinentie
O:	Betrouwbaarheid/ validiteit/ toepasbaarheid

De PICO-vraag is omgezet in zoektermen die gecombineerd zijn tot een zoekstrategie waarmee de gewenste literatuur geïdentificeerd is.

Tabel 17. Zoekstrategie Pubmed.

Onderwerp	Fecale incontinentie
#1: Incontinentie	“Fecal Incontinence”[Mesh] OR “fecal incontinence”[tiab] OR “Flatus incontinence”[tiab] OR “bowel incontinence”[tiab] OR “anal incontinence”[tiab] OR “feces incontinence”[tiab] OR encopres*[tiab] OR “anus incontinence”[tiab] OR “defecation incontinence”[tiab] OR “feacal incontinence”[tiab]
#2: Studie populatie	"Frail Elderly"[Mesh] OR "Aged, 80 and over"[Mesh] OR frail*[tiab] OR vulnerable[tiab] OR "low functioning"[tiab] OR "functional decline"[tiab] OR aging[tiab] OR ageing[tiab] OR elder*[tiab] OR old[tiab] OR older[tiab] OR geriatric*[tiab] OR "older people"[tiab] OR "community dwelling elderly"[tiab] OR "care home"[tiab] OR “community care”[tiab] OR “nursing care”[tiab] OR nurse[ad] OR nursing[ad]
# 3: Focus van de studie: Diagnostiek	"diagnosis"[Mesh] OR "diagnosis"[Subheading] OR "diagnos*"[tiab] OR “Surveys and Questionnaires”[Mesh] OR Questionnair*[tiab] OR Instrument*[tiab] OR screen*[tiab] OR ("early"[tiab] AND "detection"[tiab]) OR assessment*[tiab] OR assessing[tiab] OR self-report[tiab] OR inventory[tiab] OR scale[tiab] OR checklist*[tiab] OR form[tiab] OR tool*[tiab] OR evaluation[tiab] OR rating[tiab] OR monitor*[tiab] OR score*[tiab] OR scoring[tiab] OR index[tiab] OR indices[tiab] OR interview*[tiab] OR survey*[tiab] OR method*[tiab] OR identification[tiab] OR identif*[tiab] OR diary[tiab] OR test[tiab] OR evaluation[tiab] OR investigation[tiab]
#4: Publicatietype	Systematic review[pt] OR systematic review[tiab] OR meta-analysis[pt] OR meta-analysis[tiab] OR meta-analyses[tiab] OR meta analysis[tiab] OR meta analyses[tiab] OR metaanalysis[tiab] OR metaanalyses[tiab] OR randomized

	controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled[tiab] OR placebo*[tiab] OR trial[tiab] OR intervention[tiab] OR "Cross-Over Studies"[Mesh] OR "Double-Blind Method"[Mesh] OR "Prospective Studies"[Mesh] OR "Follow-up Studies"[Mesh] OR "Cohort Studies"[Mesh] OR crossover[tiab] OR cross-over[tiab] OR double-blind[tiab] OR doubleblind[tiab] OR single-blind[tiab] OR singleblind[tiab] OR cohort*[tiab] OR prospective[tiab] OR longitudinal[tiab] OR observational[tiab] OR follow-up[tiab] OR followup[tiab] OR effectiveness[tiab] OR safety[tiab] OR “clinical review”[tiab] OR “literature review”[tiab]
Limits	Gepubliceerd vanaf 2008
#1 AND #2 AND #3 AND #4 + limits	

Tabel 18. Zoekstrategie in Embase.

Onderwerp	Fecale incontinentie
#1: Incontinentie	‘feces Incontinence’/exp OR ‘fecal incontinence’:ti,ab OR 'Flatus incontinence':ti,ab OR 'bowel incontinence':ti,ab OR 'anal incontinence':ti,ab OR 'feces incontinence':ti,ab OR encopres*:ti,ab OR 'anus incontinence':ti,ab OR 'defecation incontinence':ti,ab OR 'feacal incontinence':ti,ab
#2: Studie populatie	‘Frail Elderly’/exp OR ‘Very elderly’/exp OR frail*:ti,ab OR 'vulnerable’:ti,ab OR ‘low functioning’:ti,ab OR 'functional decline':ti,ab OR aging:ti,ab OR ageing:ti,ab OR elder*:ti,ab OR old:ti,ab OR older:ti,ab OR geriatric*:ti,ab OR 'older people':ti,ab OR 'community dwelling elderly':ti,ab OR 'care home':ti,ab OR 'community care':ti,ab OR 'nursing care':ti,ab OR nurse:ad OR nursing:ad
# 3: Focus van de studie: Diagnostiek	’diagnosis’/exp OR ‘Diagnosis’:lnk OR diagnos*:ti,ab OR Questionnaires/exp OR Questionnair*:ti,ab OR Instrument*:ti,ab OR screen*:ti,ab OR (early:ti,ab AND detection:ti,ab) OR assessment*:ti,ab OR assessing:ti,ab OR self-report:ti,ab OR inventory:ti,ab OR scale:ti,ab OR checklist*:ti,ab OR form:ti,ab OR tool*:ti,ab OR evaluation:ti,ab OR rating:ti,ab OR monitor*:ti,ab OR score*:ti,ab OR scoring:ti,ab OR index:ti,ab OR indices:ti,ab OR interview*:ti,ab OR survey*:ti,ab OR method*:ti,ab OR identification:ti,ab OR identif*:ti,ab OR diary:ti,ab OR test:ti,ab OR evaluation:ti,ab OR investigation:ti,ab
#4: Publicatietype	‘Systematic review’/exp OR ‘systematic review’:ti,ab OR ‘meta analysis’/exp OR meta-analysis:ti,ab OR meta-analyses:ti,ab OR 'meta analysis':ti,ab OR 'meta analyses':ti,ab OR metaanalysis:ti,ab OR metaanalyses:ti,ab OR term:it OR term:it OR randomized:ti,ab OR randomised:ti,ab OR RCT:ti,ab OR controlled:ti,ab OR placebo*:ti,ab OR trial:ti,ab OR intervention:ti,ab OR 'Cross-Over Studies'/exp OR 'Double-Blind Method'/exp OR 'Prospective Studies'/exp OR 'Follow-up Studies'/exp OR 'Cohort Studies'/exp OR crossover:ti,ab OR cross-over:ti,ab OR double-blind:ti,ab OR doubleblind:ti,ab OR single-blind:ti,ab OR singleblind:ti,ab OR cohort*:ti,ab OR prospective:ti,ab OR longitudinal:ti,ab OR observational:ti,ab OR follow-up:ti,ab OR followup:ti,ab OR effectiveness:ti,ab OR safety:ti,ab OR ‘clinical review’:ti,ab OR ‘literature review’:ti,ab
Limits	Gepubliceerd vanaf 2008; Article; article in press; review
#1 AND #2 AND #3 AND #4 + limits	

Tabel 19. Zoekstrategie CINAHL.

Onderwerp	Fecale incontinentie
#1: Incontinentie	TI (“Flatus incontinence” OR “bowel incontinence” OR “anal incontinence” OR “feces incontinence” OR encopres* OR “anus incontinence” OR “defecation incontinence” OR “feacal incontinence”) OR MH “Fecal Incontinence” OR AB (“Flatus incontinence” OR “bowel incontinence” OR “anal incontinence” OR “feces incontinence” OR encopres* OR “anus incontinence” OR “defecation incontinence” OR “feacal incontinence”)
#2: Studie populatie	TI (Frail* OR vulnerable OR "low functioning" OR "functional decline" OR aging OR ageing OR elder* OR old OR older OR geriatric* OR "older people" OR "community dwelling elderly" OR "care home" OR “community care” OR “nursing care”) OR AB (Frail* OR vulnerable OR "low functioning" OR "functional decline" OR aging OR ageing OR elder* OR old OR older OR geriatric* OR "older people" OR "community dwelling elderly" OR "care home" OR “community care” OR “nursing care”) OR MH ("Frail Elderly" OR "Aged, 80 and over") OR AF ("nurse" OR "nursing")
# 3: Focus van de studie: Diagnostiek	TI (Diagnos* OR Questionnaire* OR Instrument* OR screen* OR ("early" AND "detection") OR assessment* OR assessing* OR self-report* OR inventory* OR scale* OR checklist* OR form* OR tool* OR evaluation* OR rating* OR monitor* OR score* OR scoring OR index OR indices OR interview* OR survey* OR method* OR identification OR indentif* OR diary OR test OR evaluation OR investigation) OR AB (Diagnos* OR Questionnaire* OR Instrument* OR screen* OR ("early" AND "detection") OR assessment* OR assessing* OR self-report* OR inventory* OR scale* OR checklist* OR form* OR tool* OR evaluation* OR rating* OR monitor* OR score* OR scoring OR index OR indices OR interview* OR survey* OR method* OR identification OR indentif* OR diary OR test OR evaluation OR investigation) OR MH ("diagnosis" OR “Surveys and Questionnaires”) OR MW "diagnosis"
#4: Publicatietype	TI ("Systematic review" OR "meta-analysis" OR "meta-analyses" OR "meta analysis" OR "meta analyses" OR "metaanalysis" OR "metaanalyses" OR "randomized" OR "randomised" OR "RCT" OR "controlled" OR placebo* OR "trial" OR "intervention" OR "crossover" OR "cross-over" OR "double-blind" OR "doubleblind" OR "single-blind" OR "singleblind" OR cohort* OR "prospective" OR "longitudinal" OR "observational" OR "follow-up" OR "followup" OR "effectiveness" OR "safety" OR “clinical review” OR “literature review”) OR AB ("Systematic review" OR "meta-analysis" OR "meta-analyses" OR "meta analysis" OR "meta analyses" OR "metaanalysis" OR "metaanalyses" OR "randomized" OR "randomised" OR "RCT" OR "controlled" OR placebo* OR "trial" OR "intervention" OR "crossover" OR "cross-over" OR "double-blind" OR "doubleblind" OR "single-blind" OR "singleblind" OR cohort* OR "prospective" OR "longitudinal" OR "observational" OR "follow-up" OR "followup" OR "effectiveness" OR "safety" OR “clinical review” OR “literature review”) OR MH ("Cross-Over Studies" OR "Double-Blind Method" OR "Prospective Studies" OR "Follow-up Studies" OR "Cohort Studies") OR PT ("Systematic review" OR "meta-analysis" OR "randomized controlled trial" OR "controlled clinical trial")
Limits	Gepubliceerd vanaf 2008
#1 AND #2 AND #3 AND #4 + limits	

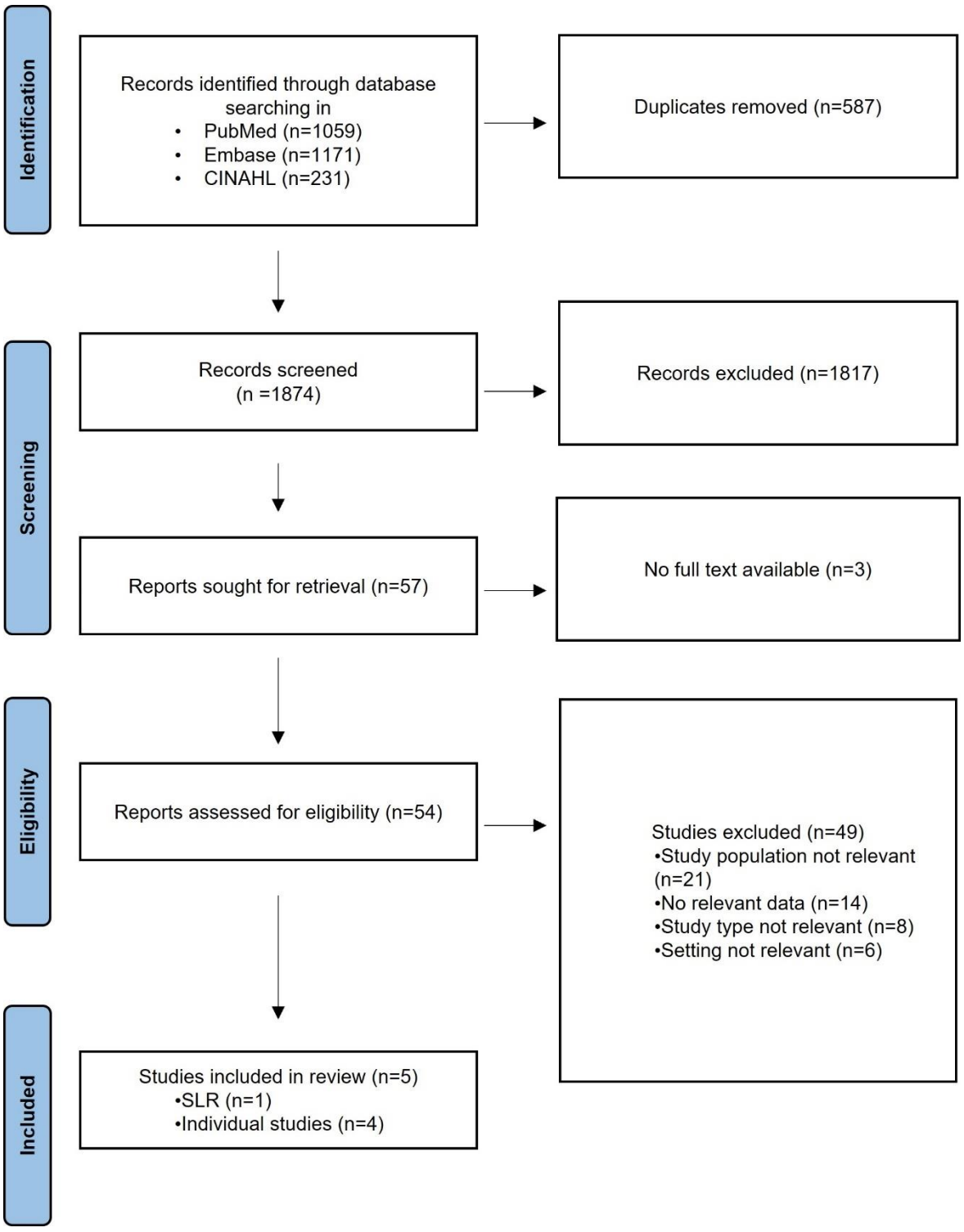
Voor de selectie van relevante artikelen zijn in- en exclusiecriteria geformuleerd. De volgende in- en exclusiecriteria zijn vastgesteld:

Tabel 20. In- en exclusiecriteria.

	Inclusie	Exclusie
Publicatieperiode	/	/
Scope	Wereldwijd	/
Taal	Engels, Nederlands	Overige talen
Studiepopulatie	Ouderen Gemiddelde leeftijd in onderzoekspopulatie ≥60 jaar	- Zwangere vrouwen - Vrouwen tijdens en voor de menopauze - Kinderen, adolescenten - Dierstudies - Mensen die al langer incontinentie zijn door een degeneratieve ziekte (MS, ALS) - Mensen met een verstandelijke beperking
Focus van de studie	Diagnostiek van fecale incontinentie: - Anamnese - Defecatiedagboek - Mictiedagboek - Anaal functieonderzoek - Vragenlijsten inventarisatie lichamelijke en cognitieve beperkingen - Vragenlijst kwaliteit van leven (fecal incontinence quality of life questionnaire) - Vragenlijst symptoomscores (Wexner score; Vaizey score; fecal incontinence severity index)	- Chirurgische ingrepen - Preventie
Studie uitkomsten	Validiteit Betrouwbaarheid Herhaalbaarheid Toepasbaarheid	
Publicatietype	Peer-reviewed artikelen	- Boek - Letter to the editor - Commentaar - Editorial - Congres abstract
Studiedesign	- Gerandomiseerde gecontroleerde studies (RCT) - Observationele studies - Literatuurreview - Meta-analyse	- Case report - Case series - Narratieve reviews

Selectie van artikelen: De selectie van titels/abstracts werd 20% dubbel uitgevoerd met behulp van de software van Rayyan. Verdere selectie van de volledige tekst werd door één onderzoeker volledig gedaan, een andere onderzoeker controleerde de geëxcludeerde artikelen. Twijfelgevallen werden samen besproken tot een consensus was bereikt. Als de inclusiecriteria niet goed toepasbaar waren, werd het artikel voorgelegd aan de werkgroep. De uitkomsten van de selectie van de volledige tekst werden in Excel geregistreerd. Voor de geëxcludeerde artikelen werd de reden van exclusie gegeven. De lijst met geëxcludeerde artikelen werd voorgelegd aan de werkgroep ter controle.

In de afbeelding hieronder wordt de selectie van de literatuur schematisch weergegeven. Uiteindelijk zijn er 6 studies geïncludeerd (1 systematische review en 4 observationele studies) die (deels) antwoord geven op de uitkomstvragen. Tabel 21 geeft de details van de geëxcludeerde studies weer.



Figuur 3. Flow-chart van de SLR-uitgangsvraag 2.

Tabel 21. Geëxcludeerde artikelen.

Reden voor exclusie	Volledige referentie
Geen relevante data (n=14)	Brown, H. W., M. E. Wise, D. Westenberg, N. B. Schmuhl, K. L. Brezoczky, R. G. Rogers and M. L. Constantine (2017). "Validation of an instrument to assess barriers to care-seeking for accidental bowel leakage in women: the BCABL questionnaire." Int Urogynecol J 28(9): 1319-1328.
	Duelund-Jakobsen, J., S. Haas, S. Buntzen, L. Lundby, G. Bøje and S. Laurberg (2015). "Nurse-led clinics can manage faecal incontinence effectively: results from a tertiary referral centre." Colorectal Dis 17(8): 710-715.
	Guallar-Bouloc, M., P. Gómez-Bueno, M. Gonzalez-Sanchez, G. Molina-Torres, R. Lomas-Vega and A. Galán-Mercant (2021). "Spanish Questionnaires for the Assessment of Pelvic Floor Dysfunctions in Women: A Systematic Review of the Structural Characteristics and Psychometric Properties." Int J Environ Res Public Health 18(23).
	Lehto, K., K. Ylönen, M. Hyöty, P. Collin, H. Huhtala and P. Aitola (2014). "Anal incontinence: long-term alterations in the incidence and healthcare usage." Scand J Gastroenterol 49(7): 790-793.
	Molina-Torres, G., L. Amiano-López, M. M. Córdoba-Peláez, A. J. Ibáñez-Vera and E. Diaz-Mohedo (2022). "Analysis of the Structural Characteristics and Psychometric Properties of the Pelvic Floor Bother Questionnaire (PFBQ): A Systematic Review." J Clin Med 11(23).
	Muñoz-Duyos, A., L. Lagares-Tena, H. Vargas-Pierolas, A. Rodón and A. Navarro-Luna (2017). "High-resolution circuit for the diagnosis of faecal incontinence. Patient satisfaction." Cir Esp 95(5): 276-282.
	Norton, C., W. E. Whitehead, D. Z. Bliss, D. Harari and J. Lang (2010). "Management of fecal incontinence in adults." Neurourol Urodyn 29(1): 199-206.
	Rao, S. S., E. Coss-Adame, K. Tantiphlachiva, A. Attaluri and J. Remes-Troche (2014). "Translumbar and transsacral magnetic neurostimulation for the assessment of neuropathy in fecal incontinence." Dis Colon Rectum 57(5): 645-652.
	Ribas, Y., M. Coll, A. Espina, C. Jiménez, M. Chicote, M. Torné and I. Modolell (2017). "Initiative to improve detection of faecal incontinence in primary care: The GIFT Project." Fam Pract 34(2): 175-179.
	Roe, B., L. Flanagan, B. Jack, J. Barrett, A. Chung, C. Shaw and K. Williams (2011). "Systematic review of the management of incontinence and promotion of continence in older people in care homes: descriptive studies with urinary incontinence as primary focus." J Adv Nurs 67(2): 228-250.
	Ross, S., H. Fast, S. Garies, D. Slade, D. Jackson, M. Doraty, R. Miyagishima, B. Soos, M. Taylor, T. Williamson and N. Drummond (2020). "Pelvic floor disorders in women who consult primary care clinics: development and validation of case definitions using primary care electronic medical records." CMAJ Open 8(2): E414-e419.
	Subramaniam, N. and H. P. Dietz (2020). "What is a significant defect of the anal sphincter on translabial ultrasound?" Ultrasound Obstet Gynecol 55(3): 411-415.
	Szojda, M. M., E. Tanis, C. J. Mulder and R. J. Felt-Bersma (2008). "Referral for anorectal function evaluation is indicated in 65% and beneficial in 92% of patients." World J Gastroenterol 14(2): 272-277.
	Trad, W., K. Flowers, J. Caldwell, M. S. Sousa, G. Vigh, L. Lizarondo, J. Gaudin, D. Hooper and D. Parker (2019). "Nursing assessment and management of incontinence among medical and surgical adult patients in a tertiary hospital: a best practice implementation project." JBI Database System Rev Implement Rep 17(12): 2578-2590.

Reden voor exclusie	Volledige referentie
Artikel niet beschikbaar (n=3)	Guinane, J. and R. Crone (2017). "Faecal incontinence in older people in Australia and New Zealand: a narrative review." Australian & New Zealand Continence Journal 23(1): 6-13.
	Shah, B. J., S. Chokhavatia and S. Rose (2012). "Fecal incontinence in the elderly: FAQ." American Journal of Gastroenterology 107(11): 1635-1646.
	Wijk, H., K. Corazzini, I. L. Kjellberg, A. Kinnander, E. Alexiou and K. Swedberg (2018). "Person-Centered Incontinence Care in Residential Care Facilities for Older Adults With Cognitive Decline: Feasibility and Preliminary Effects on Quality of Life and Quality of Care." J Gerontol Nurs 44(11): 10-19.
Setting niet relevant (n=6)	Grande, M., F. Cadeddu, P. Sileri, P. Ciano, G. M. Attinà, I. Selvaggio and G. Milito (2011). "Anal vector volume analysis: an effective tool in the management of pelvic floor disorders." Tech Coloproctol 15(1): 31-37.
	Heinrich, H., H. Fruehauf, M. Sauter, A. Steingötter, M. Fried, W. Schwizer and M. Fox (2013). "The effect of standard compared to enhanced instruction and verbal feedback on anorectal manometry measurements." Neurogastroenterol Motil 25(3): 230-237, e163.
	Leroi, A. M., C. Melchior, C. Charpentier, V. Bridoux, C. Savoye-Collet, E. Houivet, P. Ducrotté and G. Gourcerol (2018). "The diagnostic value of the functional lumen imaging probe versus high-resolution anorectal manometry in patients with fecal incontinence." Neurogastroenterol Motil 30(6): e13291.
	Melchior, C., V. Bridoux, O. Touchais, C. Savoye-Collet and A. M. Leroi (2015). "MRI defaecography in patients with faecal incontinence." Colorectal Dis 17(3): O62-69.
	Pehl, C., H. Seidl, N. Scalercio, F. Gundling, T. Schmidt, W. Schepp and S. Labermeyer (2012). "Accuracy of anorectal manometry in patients with fecal incontinence." Digestion 86(2): 78-85.
	Soh, J. S., H. J. Lee, K. W. Jung, I. J. Yoon, H. S. Koo, S. Y. Seo, S. Lee, J. H. Bae, H. S. Lee, S. H. Park, D. H. Yang, K. J. Kim, B. D. Ye, J. S. Byeon, S. K. Yang, J. H. Kim and S. J. Myung (2015). "The diagnostic value of a digital rectal examination compared with high-resolution anorectal manometry in patients with chronic constipation and fecal incontinence." Am J Gastroenterol 110(8): 1197-1204.
Studie populatie niet relevant (n=21)	Bedard, K., S. Heymen, O. S. Palsson, A. E. Bharucha and W. E. Whitehead (2018). "Relationship between symptoms and quality of life in fecal incontinence." Neurogastroenterol Motil 30(3).
	Cotterill, N., C. Norton, K. N. Avery, P. Abrams and J. L. Donovan (2011). "Psychometric evaluation of a new patient-completed questionnaire for evaluating anal incontinence symptoms and impact on quality of life: the ICIQ-B." Dis Colon Rectum 54(10): 1235-1250.
	Cotterill, N., C. Norton, K. N. L. Avery, P. Abrams and J. L. Donovan (2008). "A patient-centered approach to developing a comprehensive symptom and quality of life assessment of anal incontinence." Diseases of the Colon and Rectum 51(1): 82-87.
	Gafni-Kane, A., R. P. Goldberg, P. K. Sand and S. M. Botros (2012). "Enhanced interpretability of the PFDI-20 with establishment of reference scores among women in the general population." Neurourol Urodyn 31(8): 1252-1257.
	Heymen, S., O. Palsson, M. Simren and W. E. Whitehead (2017). "Patient preferences for endpoints in fecal incontinence treatment studies." Neurogastroenterol Motil 29(5).
	Jeppson, P. C., M. F. Paraiso, J. E. Jelovsek and M. D. Barber (2012). "Accuracy of the digital anal examination in women with fecal incontinence." Int Urogynecol J 23(6): 765-768.

Reden voor exclusie	Volledige referentie
	Kelly, S. L., S. C. Radley and S. R. Brown (2016). "Does percutaneous tibial nerve stimulation improve global pelvic function in women with faecal incontinence?" Colorectal Dis 18(5): O158-163.
	Maeda, Y., D. Parés, C. Norton, C. J. Vaizey and M. A. Kamm (2008). "Does the St. Mark's incontinence score reflect patients' perceptions? A review of 390 patients." Dis Colon Rectum 51(4): 436-442.
	Mazor, Y., G. Prott, M. Jones, J. Kellow, A. Ejova and A. Malcolm (2019). "Anorectal physiology in health: A randomized trial to determine the optimum catheter for the balloon expulsion test." Neurogastroenterol Motil 31(4): e13552.
	Mazor, Y., R. Q. Trieu, G. Prott, M. Jones, A. Ejova, J. Kellow and A. Malcolm (2021). "Volumetric Rectal Perception Testing: Is It Clinically Relevant? Results From a Large Patient Cohort." Am J Gastroenterol 116(12): 2419-2429.
	Nockolds, C. L., G. L. Hosker and E. S. Kiff (2013). "Compound muscle action potential of the external anal sphincter." Colorectal Dis 15(10): 1289-1294.
	Oom, D. M., R. L. West, W. R. Schouten and A. B. Steensma (2012). "Detection of anal sphincter defects in female patients with fecal incontinence: a comparison of 3-dimensional transperineal ultrasound and 2-dimensional endoanal ultrasound." Dis Colon Rectum 55(6): 646-652.
	Paka, C., I. Kamisan Atan, R. Rios and H. P. Dietz (2017). "Relationship of Anatomy and Function: External Anal Sphincter on Transperineal Ultrasound and Anal Incontinence." Female Pelvic Med Reconstr Surg 23(4): 238-243.
	Pinto, R. A., I. J. F. Corrêa Neto, S. C. Nahas, I. Froehner Junior, D. F. M. Soares and I. Cecconello (2019). "IS THE PHYSICIAN EXPERTISE IN DIGITAL RECTAL EXAMINATION OF VALUE IN DETECTING ANAL TONE IN COMPARISON TO ANORECTAL MANOMETRY?" Arq Gastroenterol 56(1): 79-83.
	Reddymasu, S. C., S. Singh, S. Waheed, M. Oropeza-Vail, R. W. McCallum and M. Olyaee (2009). "Comparison of anorectal manometry to endoanal ultrasound in the evaluation of fecal incontinence." Am J Med Sci 337(5): 336-339.
	Sri Pavani, B. and P. V. N. Murthy (2022). "Transperineal ultrasound versus MRI for anal sphincter dysfunction: accuracy and benefits." European Journal of Molecular and Clinical Medicine 9(7): 9718-9725.
	Voorham-van der Zalm, P. J., G. A. B. Lycklama À Nijeholt, H. W. Elzevier, H. Putter and R. C. M. Pelger (2008). ""Diagnostic investigation of the pelvic floor": a helpful tool in the approach in patients with complaints of micturition, defecation, and/or sexual dysfunction." J Sex Med 5(4): 864-871.
	Wang, Y. C., D. Deutscher, S. C. Yen, M. W. Werneke and J. E. Mioduski (2014). "The self-report fecal incontinence and constipation questionnaire in patients with pelvic-floor dysfunction seeking outpatient rehabilitation." Phys Ther 94(2): 273-288.
	Wasserberg, N., A. Mazaheri, P. Petrone, H. Tulchinsky and H. S. Kaufman (2011). "Three-dimensional endoanal ultrasonography of external anal sphincter defects in patients with faecal incontinence: correlation with symptoms and manometry." Colorectal Dis 13(4): 449-453.
	Wei, J. T., R. Dunn, I. Nygaard, K. Burgio, E. S. Lukacz, A. Markland, P. A. Wren, L. Brubaker, M. D. Barber, J. E. Jelovsek, C. Spino, S. Meikle and N. Janz (2017). "Development and Validation of a Quantitative Measure of Adaptive Behaviors in Women With Pelvic Floor Disorders." Female Pelvic Med Reconstr Surg 23(4): 232-237.
	Yan, Y., A. Sharma, A. A. Herekar, E. Jimenez, A. R. Hudgi, Q. G. Gu and S. S. C. Rao (2022). "Translumbosacral Anorectal Magnetic Stimulation Test for Fecal Incontinence." Dis Colon Rectum 65(1): 83-92.
Type studie niet relevant (n=8)	Blekken, L. E., A. Vinsnes, K. Gjeilo, S. Mørkved, Salvesen, C. Norton and S. Nakrem (2015). "Effect of a multifaceted educational program for care staff

Reden voor exclusie	Volledige referentie
	concerning fecal incontinence in nursing home patients: Study protocol of a cluster randomized controlled trial." Trials 16(1).
	Fallon, A. B., J. Westaway and C. Moloney (2014). "A systematic review of instruments for the assessment of faecal incontinence for community-dwelling older persons." JBI Library of Systematic Reviews 3(7 SUPPL.): S37-S45.
	Lee, C. and J. L. Lee (2022). "Is It a Refractory Disease?- Fecal Incontinence; beyond Medication." EWHA Medical Journal 45(4).
	Lee, Y. Y., A. Erdogan and S. S. C. Rao (2013). "High resolution and high definition anorectal manometry and pressure topography: Diagnostic advance or a new kid on the block? topical collection on neuromuscular disorders of the gastrointestinal tract." Current Gastroenterology Reports 15(12).
	Meyer, I. and L. Kissane (2017). "Epidemiology, Pathophysiology and Management of Fecal Incontinence in the Older Woman." Current Geriatrics Reports 6(2): 64-73.
	Shaw, C. and A. Wagg (2021). "Urinary and faecal incontinence in older adults." Medicine (United Kingdom) 49(1): 44-50.
	Smith, E. M. and A. A. Shah (2018). "Screening for Geriatric Syndromes: Falls, Urinary/Fecal Incontinence, and Osteoporosis." Clinics in Geriatric Medicine 34(1): 55-67.
	Solanki, D., F. Hibberts and A. B. Williams (2019). "Pelvic floor investigations for bowel dysfunction (part 2): anorectal physiology (manometry)." Gastrointestinal Nursing 17(5): 24-31.
	Fallon, A. B., J. Westaway and C. Moloney (2014). "A systematic review of instruments for the assessment of faecal incontinence for community-dwelling older persons." JBI Library of Systematic Reviews 3(7 SUPPL.): S37-S45.

Kwaliteitsbeoordeling (risk of bias) van de individuele studies

Voor de individuele artikelen over screeningsinstrumenten is de Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2)[23] gebruikt, wat ook de voorkeurstool is bij een aanpak volgens GRADE[24]. De scores per studie zijn weergegeven in Tabel 22.

Tabel 22. Risk of bias gebaseerd op QUADAS-2 tool.

Studie	RISK OF BIAS				Toepasbaarheid		
	Patiënt selectie	Index test	Referentie standaard	Flow en timing	Patiënt selectie	Index test	Referentie standaard
Zycynski-2020	☹	☹	?	☹	☹	☹	?
Lehmann-2022	☹	☹	?	☹	☹	☹	?
Rongers-2020	☹	☹	?	☹	☺	☹	?
Sansoni-2013	☺	☺	?	?	☺	?	?

☺Low Risk ☹High Risk ? Unclear Risk

Beoordeling van de kracht van het wetenschappelijk bewijs

Voor de beoordeling van de kracht van het wetenschappelijk bewijs is eerst de kwaliteit van elke individuele studie bepaald m.b.v. Quadas-2. Hoewel de toepasbaarheid van de studies over het algemeen voldoende tot goed scoorde, was “the risk of bias” in alle gevallen gemiddeld tot hoog.

Om iets te kunnen zeggen over een overall kracht van bewijs is nagegaan of er dezelfde uitkomstmaten of vergelijkingen tussen studies voorkwamen. In de meeste gevallen konden er niet meerdere studies voor één bepaalde uitkomstmaat gecombineerd worden en/of bleken vergelijkingen tussen diagnostische instrumenten niet overeen te komen tussen studies. Waardoor we toch uitkomen op de individuele beoordeling van de studies.

De gradering van bewijs voor de screeningstools/-indicatoren is uitgevoerd via een aangepaste methode gebaseerd op GRADE, waarbij per screeningstool/vergelijking/uitkomstmaat de body of evidence is beoordeeld. GRADE heeft vier niveaus van bewijs: zeer laag, laag, gematigd en hoog. Bewijs uit gerandomiseerde gecontroleerde trials starten op “hoge mate van bewijs”, vanwege risico op confounding, bewijs gebaseerd op observationele data heeft als uitgangspunt lage mate van bewijs. De mate van bewijs kan worden verhoogd of verlaagd vanwege diverse redenen, zoals risk of bias, imprecisie, inconsistentie, indirectheid, publication bias.[25]

Geïncludeerde artikelen voor deze systematische review zijn allemaal observationeel van aard (lage mate van bewijs) en hebben een moderate/high risk of bias. Vanwege het feit dat door verschillende uitkomstmaten en vergelijkingen niet meer studies met elkaar gecombineerd konden worden, is imprecisie hoog. Voor de enkele gevallen waar dit wel kon, was de inconsistentie hoog. De kracht van het wetenschappelijk bewijs was hiermee voor alle aparte screeningstools en -indicatoren zeer laag.

---

[23] Whiting PF, Rutjes AW, Westwood ME, Mallett S, Deeks JJ, Reitsma JB, Leeflang MM, Sterne JA, Bossuyt PM; QUADAS-2 Group. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med. 2011 Oct 18;155(8):529-36.

[24] Schünemann, H. J., Oxman, A. D., Brozek, J., Glasziou, P., Jaeschke, R., Vist, G. E., ... & Guyatt, G. H. (2008). Grading quality of evidence and strength of recommendations for diagnostic tests and strategies. Bmj, 336(7653), 1106-1110.

[25] https://gdt.gradepro.org/app/handbook/handbook.html

Commentaarfase en aanpassingen

Naar aanleiding van de commentaarfase zijn de volgende punten aangepast:

- Enkele tekstuele wijzigingen zijn gemaakt in de aanbevelingen en de moduletekst ten behoeve van de leesbaarheid.
- Om de aanbevelingen vergelijkbaar te maken met urine-incontinentie is de afkorting FI ook uitgeschreven als fecale incontinentie.
- De aanbevelingen over vragenlijsten zijn uitgebreid met een kleine tabel met het doel van elke vragenlijst.
- In de Overwegingen bij Organisatie van zorg is de tekst uitgebreid wat te doen bij chronische klachten. Ook is tekst toegevoegd over het delen van informatie tussen professionals. Deze tekst komt uit de overwegingen van UI.
- Er is net als bij module 1 een bijlage toegevoegd met interpretatie van de vragenlijsten.

Evidence tabellen

Author, year, country, type of study	Study objective	Study population (age; %female Setting; Type of incontinence	Inclusion and exclusion criteria	Index tool; Reference tool	Outcome measures
Zycynski-2020(Zyczynski, Richter et al. 2020) Neurourol Urodyn USA Ancillary study to RCT	To assess performance, acceptability, external validity, and reliability of a phone application electronic bowel diary (PFDN Bowel eDiary).	*Study population* **Women with refractory FI** (Mean: 63.8 years (SD: 9.8); 100%) N=60	*Inclusion criteria* Women had to own a smartphone, be willing to install the PFDN Bowel eDiary application and be willing to document 14 additional diary days during the run-in period. A minimum score of 12 on the St Mark's questionnaire was required for enrollment and for randomization to intervention group	*Index tool* eDiary (14 days): The PFDN Bowel eDiary application captures 4 elements: the time of event entry (automatic date/time stamp), event type (bowel movement (BM) without leakage, BM with leakage, or leakage only), stool consistency (Bristol Stool Scale), and presence of urgency. Urgency was defined as the sudden, compelling desire to defecate that is difficult to defer.	<u>Usability:</u> system usability scale (SUS). The SUS is a validated, 10-item questionnaire developed to differentiate between usable and unusable electronic products and services including hardware, software, mobile devices, websites, and applications. Respondents select from five Likert-type responses (Strongly Agree to Strongly Disagree) to statements such as: "I found the system unnecessarily complex"; "I felt very confident using the system"; "I think that I would like to use this system compared to a written diary to measure my bowel habits in a clinical study". The SUS is scored 0-100, higher being better, and is reliable in small sample size <u>Adherence:</u> Adherence to diary completion, defined as (a) ≥5 days during the first week, (b) ≥10 of 14 days, and (c) ≥3 consecutive days per week for both weeks. Overall adherence (i.e., a complete diary) was defined as satisfying both b and c. <u>Test-retest reliability:</u> Intraclass Correlation Coefficients (ICC)
		Setting Research center	*Exclusion criteria* - <18 years old - those who had undergone rectoanal surgery (except hemorrhoidectomy)	*Reference tool* Paper diary (14 days): same 4 elements.	
		Type of incontinence Refractory FI: failed to achieve symptom control from 2 first-line treatments: supervised pelvic muscle training and constipating medication			

Results	Conclusion and Remarks
SUS-score: The assigned sequence of diary formats had no impact on participants' overall SUS score with the mean score of 83.2 (19.5) in the group completing the eDiary first and 81.5 (15.6) in the group completing the paper diary first, (p=0.71). Most participants, 75.9% (44/58), agreed or strongly agreed that they preferred to use the eDiary compared to the paper diary to record bowel events. Adherence: Adherence to diary completion among those providing paired diaries did not differ between eDiary and paper (95.0% versus 93.3%, p=0.64). Women in the oldest tertile (>69 years) were as likely to complete eDiaries as the youngest tertile (≤62 years), 94.4% vs 95.7%. Test-retest reliability: Comparison of metrics from the first and second eDiaries found good (moderate) test-retest reliability as measured by ICC: (BMs/week = 0.81; urgency BMs/week = 0.79, FIE/week = 0.74, urgency FIE/week = 0.62)	*Conclusion* The frequency and characteristics of bowel events collected by the PFDN Bowel eDiary correlated well with the paper diary. Participants of all ages considered it easy to use and preferred it over the paper diary. The high completion rates in real-time obviated the efforts of data entry by research staff. Use in other clinical research settings needs to be assessed. *Remarks* - Multicenter study - Research setting - Limitations mentioned by the authors: participants were exclusively women who owned smartphones. *Results of quality check* - No random/consecutive patients - Exclusion criteria might introduce bias - Index vs. reference test was not performed at the same time - No threshold was defined in the methods

BM: bowel movement; FI: Fecal Incontinence; FIE: fecal incontinence episodes; ICC: intraclass correlation; RCT: Randomized controlled trial; SD: standard deviation; SUS: System Usability Scale

Author, year, country, type of study	Study objective	Study population (age; %female Setting; Type of incontinence	Inclusion and exclusion criteria	Index tool; Reference tool	Outcome measures
Lehmann-2022(Lehmann, Schreyer et al. 2022) BMC Med Austria Non-comparative study (pilot study)	To evaluate the usability of the eDiary for patients with FI; To migrate the paper-based version of the diary to an eDiary and compare the two versions; To collect feedback to improve the eDiary for use in future clinical trials.	*Study population* **Patients with a diagnosis of FI** (Mean: 67.4 years (SD: 10.7); 79%) N=23 (n=14) *Setting* Hospital (initial assessment) and home (follow-up assessment) *Type of incontinence* FI: not further specified	*Inclusion criteria* A diagnosis of FI, German language fluency, basic computer literacy and internet access at home, and providing informed consent. *Exclusion criteria* NR	*Index tool* eDiary: assessment of FI and bowel movements according to the Bristol Stool Chart. *Reference tool* Paper diary: same as eDiary.	<u>Usability</u>: system usability scale (SUS), a 10-item questionnaire using a 5-point Likert scale evaluating users' perceived system satisfaction, including two sub-scales of usability and learnability. Scores range from 0 to 100. A score of 70 points was used as a threshold for acceptable usability <u>Comparison with paper-pencil diary</u>: Questionnaire

Results	Conclusion and Remarks
<u>SUS score:</u> - Hospital: Mean SUS 87.5 points (SD 17.8, 95% CI 78.2–96.8) 84% gave rating >70 points	*Conclusion* Patients reported high satisfaction and high usability ratings for the eDiary. The majority of patients reported preferring the electronic version over a paper–pencil version. *Remarks*

- Home (2 days of use): mean SUS 97.2 points (SD 6.7, 95% CI 92.8–100). 100% gave rating >70 points <u>Comparison paper-pencil diary:</u> - Hospital: 71% prefer eDiary, 71% found eDiary easier to use, 79% saw no major differences between versions	- Patients did not use a paper-pencil diary during the study but were asked whether they would prefer eDiary over paper-pencil version - The sampling strategy purposely included some patients with low smartphone literacy or without a smartphone - Some patients required in-person assistance for app installation - 5 patients did not participate in follow-up (home) assessments for reasons: not owning a smartphone (n = 2), insufficient smartphone literacy (n = 1), a lack of time (n = 1), and technical difficulties (n = 1). *Results of quality check* - No random/consecutive patients - Exclusion criteria might introduce bias - Index vs. reference test was not performed on the same time - No threshold was defined in the methods

FI: Fecal Incontinence; NR: Not reported; SD: standard deviation; SUS: System Usability Scale

Author, year, country, type of study	Study objective	Study population (age; %female Setting; Type of incontinence	Inclusion and exclusion criteria	Index tool; Reference tool	Outcome measures
Rogers-2020(Rogers, Sung et al. 2020) Dis Colon Rectum USA	To create a valid measure of accidental bowel leakage symptoms	*Study population* **Women with a diagnosis of ABL** (Mean: 63.8 years (SD: 1.4); 100%) N=296	*Inclusion criteria* Women were eligible for participation in the focus groups and cognitive interviews if they were >/= 18 years of age, diagnosed with ABL, had bothersome ABL symptoms for at least 3 months, and were able to speak, read and comprehend English.	*Index tool* ABLE (Accidental Bowel Leakage Evaluation) – a measure of ABL capturing patient-centered symptoms. An 18-item scale grouped into 7 subscales including the specific type of leakage (solid stool, liquid stool, mucus, and gas), conditions when leakage occurs (predictability/awareness and control), and ancillary bowel symptoms.	Confirmatory factor and item response theory analyses to confirm framework and select items. <u>Reliability</u>: Cronbach α and ICC between two test measurements. <u>Construct validity:</u> based on correlations with measures of similar constructs.

Ancillary study to RCT		*Setting* Outpatient clinics *Type of incontinence* Accidental bowel leakage (not further specified)	*Exclusion criteria* Women were excluded if they reported either watery stools (consistent with a Bristol Stool Index designation of "7") or hard, lumpy stools (Bristol Stool Index designation of "1"). In addition, women were excluded if they had diagnosis or history of colorectal or anal malignancy, inflammatory bowel disease, rectovaginal fistula, rectal prolapse or history of pelvic floor or abdominal radiation.	*Reference tool* Bowel diaries, PFDI & subscales, PFIQ & subscales, the Fecal Incontinence Adaptation Index, and the SF-12	

Results	Conclusion and Remarks
<u>Reliability:</u> - Test-test reliability (ICC): Overall 0.80; subscales 0.63 (Mucus) to 0.78 (Ancillary Bowel Symptoms) - Internal consistency (Cronbach's α): Overall 0.77 at baseline to 0.90 at 24 weeks; for subscales nearly all at or above 0.70. <u>Construct validity:</u> - Bowel diaries: ABLE scores were positively related to average number of leaks (r=0.32 to 0.36) and pad changes per day (r=0.31 to 0.38) and negatively related to the number of accident-free days per week (r=−0.30 to −0.48). - Others: ABLE scores are more highly correlated with the CRADI, CRAIQ, and Fecal Adaptation Index and less highly correlated with the quality of life measures not focused on bowel symptoms, such as the SF-12.	*Conclusion* ABLE is a reliable, patient-centered measure with good validity properties. It improves on currently available measures by adding patient-important domains of predictability, awareness, control, emptying, and discomfort *Remarks* - Included women recruited to an ongoing trial comparing treatments for ABL, from eight diverse clinical sites. - Limitations: only included women seeking care for ABL for validity testing, validity is untested in men *Results of quality check* - No random/consecutive patients - Exclusion criteria might introduce bias - Index vs. reference test was not performed on the same time - No threshold was defined in the methods

ABL: Accidental Bowel Leakage; ABLE: Accidental Bowel Leakage Evaluation; CRADI: Colorectal Anal Distress Inventory; CRAIQ: Colorectal Anal Impact Questionnaire; FI: Fecal Incontinence; ICC: intraclass correlation; PFDI: Pelvic Floor Distress Inventory; PFIQ: Pelvic Floor Impact Questionnaire; RCT: Randomized controlled trial; SD: standard deviation; SF-12: Short Form-12

Author, year, country, type of study	Study objective	Study population (age; %female Setting; Type of incontinence	Inclusion and exclusion criteria	Index tool; Reference tool	Outcome measures
Sansoni-2013(Sansoni, Hawthorne et al. 2013) Dis Colon Rectum Australia Before & after study	To validate the RFIS	*Study population* **Patients seeking treatment for FI** NR; 64% ≥ 60 years; 84% N=61 (baseline) 38 (follow-up)	*Inclusion criteria* Attendance at a clinic to receive treatment for fecal incontinence, age between 18 and 85 years, and having sufficient English to complete a self-report questionnaire	*Index tool* Revised Faecal Incontinence Scale (RFIS): consists of 5 items concerning liquid- and solid-stool leakage and leakage altering lifestyle (from the Wexner) and 2 other items concerning stool leakage associated with urge and soiling of undergarments. Consistent with the ICS definition of fecal incontinence, there is no item assessing flatus. Scoring is by summation (range: 0–20 with 0 indicating no incontinence).	<u>Reliability</u>: Cronbach's α. Test-retest reliabilities: ICC. <u>Validity</u>: correlations with the Wexner and SMIS. <u>Evaluative function</u>: Pre- and posttreatment changes were reported by using Kazis' Effect Size and interpreted by using Cohen criteria where 0.20 represents a small effect, 0.50 a moderate effect, and 0.80 a large effect. Comparisons between measures were made by using the relative efficiency (RE) statistic.
		Setting Community or hospital continence clinics (n=6)	*Exclusion criteria* NR	*Reference tool* Wexner Continence Scale and St Mark's incontinence Score (SMIS)	
		Type of incontinence 58% passive incontinence; 50% urge incontinence; 50% fecal seepage			
Results				Conclusion and Remarks	

Reliability: - Cronbach's α = 0.78 compared with 0.65 for both the Wexner and SMIS. - test-retest ICC at 2 weeks post-completion of treatment (n=19) was 0.79 for the RFIS, 0.74 for the Wexner, and 0.68 for the SMIS. Validity: The pretreatment correlation of RFIS with the Wexner was r = 0.88 (p < 0.01); and with the SMIS r = 0.85 (p < 0.01) Evaluative function: All 3 instruments were similarly responsive to change at follow-up - Expressed as Kazis Effect Sizes, the score changes were ES = –0.66 (95% CI: –2.15 to +0.82) for RFIS, –0.57 (95% CI: –2.08 to +0.94) for the Wexner and –0.65 (95% CI: –2.39 to +1.09) for the SMIS. The relative efficiency of the measures was Wexner RE = 1.00, SMIS RE = 1.71 and the RFIS RE = 1.49.	*Conclusion* The RFIS possessed evaluative discrimination between different levels of incontinence severity. In this sample it had superior internal consistency and test-retest reliability to the Wexner and St Mark's Incontinence Scales. It was at least as responsive as the Wexner and St Mark's in detecting change in incontinence status following treatment. Although ongoing clinical validation is required, these findings suggest it is a short, reliable, and valid scale that could be considered for use by researchers, epidemiologists, and clinicians. *Remarks* - Patients received conservative treatments - Consecutive patients - Small sample size *Results of quality check* - Consecutive patients - Threshold was reported

CI: Confidence intervals; FI: Fecal Incontinence; ICC: intraclass correlation; NR: Not reported; RE: relative efficiency; RFIS: Revised Faecal Incontinence Scale; SMIS: St Mark's Incontinence Score

Author, year, journal, country, type of study	Study objective	Type of incontinence; Diagnostic tool	Inclusion and exclusion criteria	Search strategy, number of included studies, study outcome measures

Fallon, 2008 (Fallon, Westaway et al. 2008) Int J Evid Based Healthc Worldwide SLR	To determine what is required in an assessment of FI issues for older community-dwelling adults; and to determine the psychometric tools most effective for assessment of FI in older community-dwelling adults	*Type of incontinence* FI, including the inability to control flatus *Diagnostic tool* Psychometric tools used in the community setting	*Inclusion criteria* • Primarily concerned with people living in the community • Included a significant proportion of the sample aged ≥65 years • Examined the psychometric properties of the assessment tools or assessed sensitivity of the assessment tool to non-surgical interventions that would be available in the community setting *Exclusion criteria* • Non-English language articles, abstracts and unpublished studies • Insufficient overlap between the age range of the sample and the population of interest • Studies specific to the residential aged care, palliative care or acute settings • Studies of sensitivity of assessment tools where the treatment could only be provided in acute care settings • Studies investigating assessment in relation to pre- and post-surgical intervention • Studies relating to animals • Studies specific to a particular condition or disease, such as spina bifida	*Search strategy* CINAHL, Australian Medical Index, Embase, The Cochrane Library Pubmed/Medline, Psychlit, DARE; No limit on publication date. Date of search not reported. Search strategy reported in article. Reference lists of relevant articles were also searched. No PRISMA flow chart presented in article. *Numbers of included articles* **SLR**: 16 articles on 13 different psychometric tools ➔ 12 articles on 11 different tools were relevant for the V&VN guideline *Study outcome measures* Data relating to the psychometric validity of the targeted assessment tools (i.e. reliability validity, sensitivity, specificity)

Results	Conclusion and Remarks
FIQLS (n=3 studies) Contains 29 items scored on a 5-point Likert-type rating system and grouped into four subscales (Embarrassment, Lifestyle, Coping and Depression) • Test-retest reliability: no significant differences between test and retests (n=1 study); good intraclass coefficients (ICC) for all domains, ranging between 0.80 – 0.93 (n=2 studies), except for Embarrassment subscale (0.72 in one study). • Internal consistency: good to excellent for the Lifestyle, Behaviour and Depression/Self-Perception subscales (Cronbach a-values between 0.80 and 0.96) (n=3 studies). Values for the Embarrassment subscale were also good in 2 studies but less in the third study.	*Conclusion* The authors conclude that the Vaizey and Wexner scales are the tools of choice for assessment of AI symptom severity, and that the FIQLS is the tool of choice for measuring AI quality of life, though more work still needs to be done on demonstrating the validity of these tools. *Remarks* - Four studies from the SLR were not included for data extraction as the mean age was <60 years. This included one study on the Vaizey scale and two on the Wexner scale.

• Context and face validity: found to be clear, understandable and acceptable (n=2 studies) • Construct validity: Significantly correlated with SF-36 scale, with r ranging between 0.28-0.65 for the various subscales (n=2 studies) • Convergent validity: All subscales were observed to correlate with the Wexner score, with r ranging between 0.31-0.46 for the various subscales (n=1 study) • Validity of the factor structure: Evidence for this provided in n=2 studies • Criterion-related validity: Significant differences in scores between groups with AI and controls (n=1 study), patients with change in status after treatment (n=1 study) and patients who reported wearing pads and those who didn't wear pads (n=1 study) **Wexner (Cleveland) scale (n=1 study)** A five-item scale of symptom severity. Ratings are made as to the frequency of incontinence of solids, liquid, flatus, wearing of pads and alteration to lifestyle on a scale of 0 (never) to 4 (always). Overall, scores range between 0 (no incontinence) and 20 (complete incontinence). • Sensitivity: sufficient sensitivity to detect significant differences between before and after scores of most patients who underwent rehabilitation (n=1 study) **Vaizey (St Mark's) scale (n=1 study)** Modified Wexner scale, incorporating assessment of the ability to defer and the taking of constipating medications while reducing the importance in the need to wear a pad or plug. Total scores range from 0 (perfect continence) to 24 (total incontinence). • Sensitivity: good relationship between patient perceptions of improvement in symptoms and changes in score (n=1 study) **FISI (n=1 study)** A four-item scale. The frequency of incontinence episodes for flatus, mucus, liquid stool and solid stool in the past month is rated using a six-item scale that ranges between 'never' and 'two or more times a day'. Scores derived from the scale range between 0 (least severe) to 64 (most severe). • Convergent validity: correlation with scores on three of the four subscales of the FIQLS (Lifestyle, r = 0.45;Coping/Behaviour, r = 0.29; and Embarrassment, r =0.38). **Miller scale of continence severity (n=1 study)**	The studies demonstrated good test-retest reliability and convergent validity of the scales, and are part of the evidence supporting the authors' conclusions. - One instrument was not included for data extraction as it was specific to conditions not relevant to the V&VN guideline (Hirschsprung's Disease Anorectal Malformation Quality of Life Questionnaire) - The level of credibility (unequivocable/credible/unsupported) was judged as credible for the majority of studies, with one study assigned unsupported. The main limitation reported was small sample size (n<200 for most studies). - The article also included a review of expert opinion, aimed at determining what is required in an assessment of AI issues for older community-dwelling adults *Results of AMSTAR* - Statement of pre-defined protocol (no) - Comprehensive literature study (no) - Data extraction in duplicate (no) - Included studies described in adequate detail (partial yes) - Sources of funding for included studies (no) - Meta-analyse: nvt o Appropriate methods for statical combination (nvt) o Impact of RoB (nvt) o Heterogeneity (nvt) o Publication bias (nvt) - Conflict of interest (no)

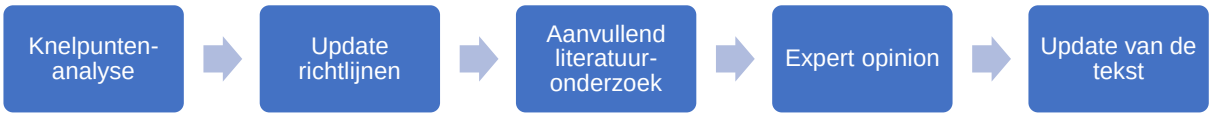
A three-item scale (flatus, liquid stool, solid stool) with frequencies ranging from less than once a month to more than once a week and total scores ranging between 0 and 18. • Sensitivity: could detect changes in symptom severity after conservative treatment, with 40% demonstrating a significant improvement in scores **International Consultation on Incontinence Questionnaire - Bowel Incontinence (ICIQ-BI) (n=1 study)** A 56-item scale in which 16 items measure aspects of symptom severity and the remainder of items measure the impact of bowel symptoms on quality of life. • Content validity: Expert review and patient interviews indicated that items were easy to interpret and covered all necessary domains. **Direct questioning of objectives (n=1 study)** A quality of life assessing methodology. Clients list objectives important to them, such as shopping or working. The client then rates the importance of topics, and how well they can perform them, both on a scale of 0-10. The product of importance and ability is divided by 10 and then by the total importance of objectives and used to create an index score between 0 and 1. • Convergent validity: decreased scores on the Vaizey and Pescatori scales correlated with increased scores on the Direct Questioning of Objectives scale, and improvements on a visual analogue completed by physicians • Sensitivity: sufficiently sensitive to detect changes due to treatment **Manchester Health Questionnaire (MHQ) (n=1 study)** A generic quality of life scale assessing general perception of health, general impact of incontinence, role, physical function, social function, personal relationships, emotion, sleep/ energy and severity/coping measures, with a separate scale for the measurement of the severity of symptoms. It uses a five-point scoring system. Scores in each domain range between 0 and 100, with a higher score indicating a greater impairment of health-related quality of life. • Test-retest reliability: correlations acceptable, with r ranging from 0.81 to 0.92 • Internal consistency: Adequate for all subscales, with chronbach-α ranging from 0.73 to 0.91 • Content validity: Reviewed and adapted for representativeness, appropriateness and understandability	

• Convergent validity: Modest to strong correlations with SF-36, with r ranging from 0.35 to 0.77 **Medical Outcomes Survey (n=1 study)** Precursor to the SF-36. Contains 149 items measuring a total of 35 dimensions of quality of life, including physical functioning, role limitations due to physical and emotional health and cognitive functioning. • Criterion-related validity: Participants with AI were observed to have similar MOS scores to participants with other colonic symptoms but had lower overall scores compared with asymptomatic controls. **EuroQol 5-D (n=1 study)** A utility measure designed for use in cross-cultural comparisons. The measure has five items, each with three response levels, and measures mobility, self-care, usual activities, pain/discomfort and nxiety/depression • Criterion-related validity: No changes observed in scores in AI patients after pelvic floor rehabilitation **Bliss stool classification scale (n=1 study)** Has four classifications of stool (hard and formed, soft and formed, loose and unformed, and liquid) • Criterion-related validity: The mean percentage of water from stools in each category was indeed found to be significantly different and a moderate relationship between participants' classifications of stools and the mean percentage of stool water was observed (r = 0.50).	

Verantwoording Uitgangsvraag 3a – Niet-medicamenteuze behandelinterventies voor urine-incontinentie

In de oude richtlijn Urine-incontinentie bij kwetsbare ouderen was al een uitgangsvraag opgenomen over niet-medicamenteuze behandelinterventies. De knelpuntenanalyse concludeerde in 2018 dat de tekst uit de oude richtlijn over te nemen in de update van de richtlijn, maar vereenvoudigd en verduidelijkt waar dat nodig is. Er moest daarbij opgelet worden of de genoemde interventies in de oude V&VN richtlijn uitgevoerd kunnen worden door de wijkverpleging of dat deze beter tot zijn recht komen bij andere disciplines.

Om te onderzoeken of er inderdaad geen nieuwe interventies ontwikkeld zijn of aanbevelingen voor bestaande interventies aangepast moeten worden, en of alle interventies door de wijkverpleging worden uitgevoerd in onderstaande aanpak gevolgd. Er is onderzocht of nieuwe literatuur en geüpdatete richtlijnen aanleiding geven om de aanbevelingen uit de oude V&VN richtlijn (2010) aan te passen. Met de werkgroep is gesproken over de uitvoerbaarheid van interventies door de wijkverpleging.



Figuur 4. Schematische weergave van de methodiek.

Van knelpuntenanalyse naar richtlijnontwikkeltraject

Uit de knelpuntenanalyse kwam naar voren dat het niet aannemelijk zou zijn dat er veel nieuw bewijs beschikbaar is over niet-medicamenteuze interventies en dat het niet voor de hand ligt dat de aanbevelingen in de richtlijnen inhoudelijk veranderen. Uit de inventarisatie onder professionals bleek het gebrek aan tijd een belangrijk knelpunt te zijn. Ook werd er genoemd dat niet alle patiënten cognitief in staat zijn de interventies op te volgen. In de oude richtlijn was hier al aandacht voor en werden een aantal voorwaarden genoemd waaraan kwetsbare ouderen moeten voldoen om bekkenbodemspiertrainingen te kunnen volgen.

Een oriënterende zoekactie tijdens de knelpuntenanalyse liet zien dat de inhoud met betrekking tot toiletgang en leefstijlinterventies geen update zou behoeven.

Wetenschappelijke literatuur

De tekst en aanbevelingen uit de oude V&VN richtlijn zijn gebaseerd op een systematische literatuurreview. Er werd literatuur tot 2008 verzameld en beoordeeld. Aangevuld met aanbevelingen en overwegingen uit richtlijnen. In de oude richtlijn werden vier groepen niet-medicamenteuze interventies onderscheiden:

- bekkenbodemspiertraining;
- blaastraining;
- leefstijladviezen;
- interventies gericht op toiletgang en toilethouding.

De werkgroep is van mening dat de eerste twee interventies in het domein van de fysiotherapie thuishoren en daarom buiten de scope van deze richtlijn voor wijkverpleging vallen. Daarom heeft de werkgroep gekozen om de literatuur over deze onderwerpen geen update te geven en alleen een

korte beschrijving van de interventies toe te voegen. Voor leefstijladviezen en interventies gericht op toiletgang is wel onderzocht of er nieuwe relevante literatuur beschikbaar is.

De (internationale) richtlijnen die in de oude V&VN richtlijn werden gebruikt hebben een update gekregen. Niet alle recente richtlijnen bevatten echter ook een recent literatuuronderzoek. De richtlijnontwikkelaars van desbetreffende richtlijnen vonden dat niet altijd noodzakelijk. Bijvoorbeeld, in de richtlijn van NICE wordt aangegeven welke aanbevelingen een update hebben gekregen. In de richtlijn van NICE zijn drie aanbevelingen opgesteld over *Lifestyle interventions*; deze zijn onveranderd sinds 2006. Twee aanbevelingen over *Behavioural therapies* zijn ook niet aangepast sinds 2006.

In Tabel 23 zijn de gebruikte richtlijnen weergegeven met daarbij of zij nieuwe literatuur bevatten ten opzichte van de oude V&VN richtlijn. In Tabel 24 is ook de kwaliteitsbeoordeling met AGREE II-GRS weergegeven.

Er is onderzocht of de richtlijnen recente relevante literatuur hebben gebruikt om tot hun aanbevelingen voor toiletgang of leefstijladviezen te komen. Met relevante literatuur wordt bedoeld: passend bij de inclusie- en exclusiecriteria die in de literatuurreview van deze V&VN richtlijn worden gebruikt. Bijvoorbeeld of studies zijn uitgevoerd in relevante patiëntengroepen. Als een richtlijn gebruikmaakte van een SLR of meta-analyse dan werd bekeken welke studies daarin geïncludeerd waren en of dat nieuw bewijs zou kunnen opleveren. Er bleek geen nieuwe recente en relevante literatuur beschikbaar.

Tabel 23. Nieuwe richtlijnen met niet-medicamenteuze interventies.

Auteur (jaar)	Titel	Toiletgang	Leefstijl	Overige opmerkingen
The National Institute for Health and Care Excellence (NICE) (2019)	Urinary incontinence, the management of urinary incontinence in women	> niet omschreven	Cafeïne > geen update Vochtinname > geen update Overgewicht > geen update Roken > niet omschreven	Een commissie beslist jaarlijks of een onderwerp een update van de literatuur nodig heeft
European Association of Urology (EAU) (2020)	Urinary Incontinence in Adults	Prompted voiding > geen nieuwe literatuur relevant voor deze richtlijn	Cafeïne > geen nieuwe literatuur Vochtinname > geen Overgewicht >geen Roken > geen	
Federatie medisch specialisten (FMS) (2014)	Urine-incontinentie (UI) 2e- en 3e-lijnszorg	1 SLR Flanagan et al. > verouderde studies Cochrane review uit 2009 > verouderde studies	Cafeïne > geen nieuwe literatuur Vochtinname > geen Overgewicht > geen	De Werkgroep heeft de EAU 2013 richtlijn als uitgangspunt genomen voor het ontwikkelen van een Nederlandse richtlijn

			Roken >geen	
Nederlandse Vereniging voor Obstetrie en Gynaecologie NVOG (2011, update 2014)	Urine-incontinentie (UI) bij vrouwen	1 SLR Flanagan et al.> verouderde studies	Cafeine > 1 NHS study Vochtinname > geen Overgewicht > geen Roken > geen	

Tabel 24. Beoordeling nieuwe richtlijnen met AGREE II-GRS score (1= lowest quality; 7= highest quality).

NICE (2019): Urinary incontinence and pelvic organ prolapse in women: management		
Item	Description	Score (1= lowest quality; 7= highest quality)
5. Rate the overall quality of the guideline Development methods	Consider: Were the appropriate stakeholders involved in the development of the guideline? Was the evidentiary base developed systematically? Were recommendations consistent with the literature?	6
6. Rate the overall quality of the guideline presentation	Consider: Was the guideline well organized? Were the recommendations easy to find?	6
7. Rate the completeness of reporting.	Consider: Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?	6
8. Rate the overall quality of the guideline recommendations	Consider: Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?	6
Rate the overall quality of the guideline.		6

EAU (2020): Urinary incontinence in adults		
Item	Description	Score (1= lowest quality; 7= highest quality)

5. Rate the overall quality of the guideline Development methods	Consider: Were the appropriate stakeholders involved in the development of the guideline? Was the evidentiary base developed systematically? Were recommendations consistent with the literature?	6
6. Rate the overall quality of the guideline presentation	Consider: Was the guideline well organized? Were the recommendations easy to find?	5
7. Rate the completeness of reporting.	Consider: Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?	5
8. Rate the overall quality of the guideline recommendations	Consider: Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?	6
Rate the overall quality of the guideline.		5

FMS (2014): Urine-incontinentie (UI) 2e- en 3e-lijnszorg		
Item	Description	Score (1= lowest quality; 7= highest quality)
5. Rate the overall quality of the guideline Development methods	Consider: Were the appropriate stakeholders involved in the development of the guideline? Was the evidentiary base developed systematically? Were recommendations consistent with the literature?	6
6. Rate the overall quality of the guideline presentation	Consider: Was the guideline well organized? Were the recommendations easy to find?	6
7. Rate the completeness of reporting.	Consider: Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?	6
8. Rate the overall quality of the guideline recommendations	Consider: Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?	6
Rate the overall quality of the guideline.		6

NOVG (2011, update in 2014): Urine-incontinentie (UI) bij vrouwen		
Item	Description	Score (1= lowest quality; 7=

		highest quality)
1. Rate the overall quality of the guideline Development methods	Consider: Were the appropriate stakeholders involved in the development of the guideline? Was the evidentiary base developed systematically? Were recommendations consistent with the literature?	6
2. Rate the overall quality of the guideline presentation	Consider: Was the guideline well organized? Were the recommendations easy to find?	4
3. Rate the completeness of reporting.	Consider: Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?	4
4. Rate the overall quality of the guideline recommendations	Consider: Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?	6
Rate the overall quality of the guideline.		5

Quick scan literatuur

De nieuwste richtlijnen zijn uit 2019 en 2020. De aanbevelingen in de geüpdatete richtlijnen zijn weinig veranderd ten opzichte van eerdere versies die gebruikt zijn bij het opstellen van de oude V&VN richtlijn. Samen met de oriënterende literatuursearch uit de knelpuntenanalyse bevestigt dit dat er weinig wetenschappelijk bewijs is dat de aanbevelingen van richting zal doen veranderen.

Omdat de geüpdatete richtlijnen ook alweer een aantal jaren geleden zijn opgesteld is er gezocht in de literatuur met een specifieke en beknopte zoekactie om te kijken of er sinds de nieuwste internationale richtlijnen nieuw bewijs is gepubliceerd. Dit literatuuronderzoek is uitgevoerd in het jaar 2023 (d.d: 11-07-2023). Er is gezocht in Medline (via Pubmed).

Volgens de AQUA-leidraad[26] is elke uitgangsvraag vertaald in een PICO vraag, die het probleem of patiënt/populatie (P), de interventie (I), de vergelijking (comparison, C) en de gewenste uitkomstmaat (outcome, O) beschrijven. In Tabel 25 staat de PICO-vraag uitgewerkt voor uitgangsvraag 3a.

Tabel 25. PICO bij uitgangsvraag niet-medicamenteuze interventies bij urine-incontinentie.

P:	Ouderen met urine-incontinentie, gemiddelde leeftijd in populatie ≥60 j
I:	Niet-medicamenteuze behandelinterventies zoals: bekkenbodemspiertraining, advies over leefstijl (o.a. overgewicht, vochtinname) en advies over toiletgang
C:	Elke vergelijking (Ander soort behandeling/geen behandeling)
O:	Relevante uitkomstmaten: - Ervaren kwaliteit van leven door de zorgvrager - Ervaren gezondheid door de zorgvrager - Ervaren hinder door de zorgvrager als gevolg van urine-continentieproblemen - Ervaren verbetering door de zorgvrager - Symptoomscores (incontinence impact questionnaire; urogential distress inventory) - Grootte van de zorgvraag

[26] https://www.zorginzicht.nl/ontwikkeltools/ontwikkelen/aqua-leidraad

De PICO-vraag is omgezet in zoektermen die gecombineerd zijn tot een zoekstrategie waarmee de gewenste literatuur geïdentificeerd is.

Tabel 26. Zoekstrategie Pubmed

Onderwerp	
#1: Incontinentie	urinary incontinence[Mesh] OR urinary incontinence[tiab] OR "urine incontinence"[tiab]
#2: Studie populatie	"Frail Elderly"[Mesh] OR "Aged, 80 and over"[Mesh] OR frail*[tiab] OR elder*[tiab] OR geriatric*[tiab]
# 3: Focus van de studies: Behandelinterventies	"Behavior Therapy"[Mesh] OR "Cognitive training"[Mesh] OR "conservative interventions"[tiab] OR "Toilet Training"[Mesh] OR "habit training"[tiab] OR "habit retraining"[tiab] OR "timed voiding"[tiab] OR "prompted voiding"[tiab] OR "Life Style"[Mesh] OR "appliances"[tiab] OR "Patient Education as Topic"[Mesh] OR "continence promotion"[tiab] OR "toileting"[tiab] OR "Fluid Therapy"[Mesh] OR "toilet training"[tiab] OR "physical therapy"[tiab] OR "continence advice"[tiab] OR "functional incidental training"[tiab] OR "urge response"[tiab] OR "Pelvic Floor"[Mesh] OR "pelvic floor muscle"[tiab] OR Biofeedback[tiab]
#4: Publicatietype	randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled[tiab] OR placebo*[tiab] OR trial[tiab] OR intervention[tiab] OR "Cross-Over Studies"[Mesh] OR "Double-Blind Method"[Mesh] OR "Prospective Studies"[Mesh] OR "Follow-up Studies"[Mesh] OR "Cohort Studies"[Mesh] OR crossover[tiab] OR cross-over[tiab] OR double-blind[tiab] OR doubleblind[tiab] OR single-blind[tiab] OR singleblind[tiab] OR cohort*[tiab] OR prospective[tiab] OR longitudinal[tiab] OR observational[tiab] OR follow-up[tiab] OR followup[tiab] OR effectiveness[tiab] OR safety[tiab]
Limits	Publication date 01/01/2008 – 11/07/2023
#1 AND #2 AND #3 AND #4 + limits	

Voor de selectie van relevante artikelen zijn in- en exclusiecriteria geformuleerd. De volgende in- en exclusiecriteria zijn vastgesteld:

Tabel 27. In- en exclusiecriteria.

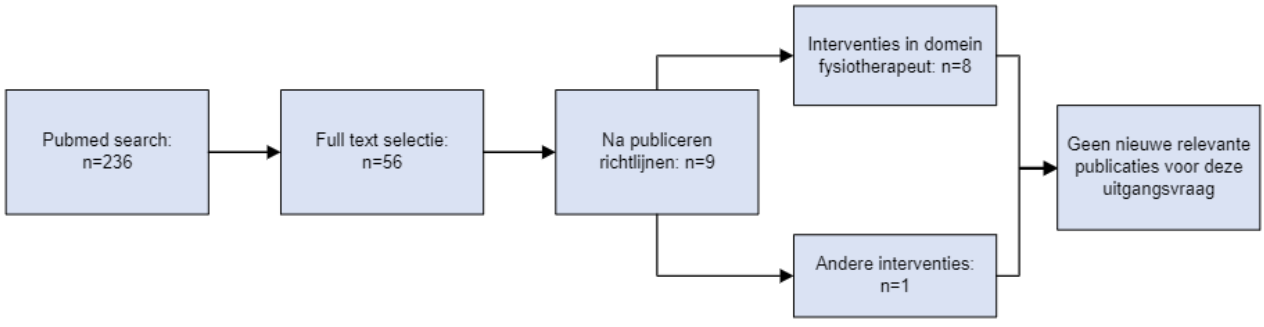
	Inclusie	Exclusie
Publicatieperiode	/	/
Scope	Wereldwijd	/
Taal	Engels, Nederlands	Overige talen
Studiepopulatie	Ouderen, Gemiddelde leeftijd in onderzoekspopulatie ≥60 jaar	- Zwangere vrouwen - Vrouwen tijdens en voor de menopauze - Kinderen, adolescenten - Dierstudies - Mensen die al langer incontinentie zijn door een degeneratieve ziekte (MS, ALS) - Mensen met een verstandelijke beperking
	Verpleegkundigen en verzorgenden werkzaam in de wijk	Professionals niet werkzaam in de wijk
Focus van de studie	Behandelinterventies:	- Chirurgische ingrepen

	- Bekkenbodemspiertraining - Advies over leefstijl (o.a. overgewicht, vochtinname) - Toiletgang na attenderen - Verbeteren gewoonte toiletgang - Vaste toiletrondes	- Medicamenteuze behandeling - Preventie - Diagnostiek - Interventie niet toepasbaar in de wijk
Studie uitkomsten	- Ervaren kwaliteit van leven door de zorgvrager - Ervaren gezondheid door de zorgvrager - Ervaren hinder door de zorgvrager als gevolg van urine-continentieproblemen - Ervaren verbetering door de zorgvrager - Symptoomscores (incontinence impact questionnaire; urogential distress inventory) - Grootte van de zorgvraag	
Studieresultaten	Nieuwe methoden of nieuwe resultaten	Herhaling van wat bekend is uit oudere onderzoeken
Publicatietype	Peer-reviewed artikelen	- Boek - Letter to the editor - Commentaar - Editorial - Congres abstract
Studiedesign	- Gerandomiseerde gecontroleerde studies (RCT) - Observationele studies	- Case report - Case series - Narratieve reviews - Literatuur review - Meta-analyse

In totaal zijn 56 studies geselecteerd op basis van titel en abstract (zie tabel onderaan in bijlage). Daarvan waren er 47 gepubliceerd voor en negen na de laatste revisie van de European Association of Urology-richtlijrn (Burkhard 2020). Deze laatste negen zijn bekeken op relevantie voor de huidige richtlijn. Artikelen over de uitvoering van bekkenbodemspiertraining of behandelingen met neurostimulatie zijn niet verder bekeken omdat de precieze uitvoering van deze vormen van therapie volgens de werkgroep buiten de scope van deze richtlijn valt omdat het geen verpleegkundige interventies zijn.

Van deze negen leek één artikel over een andere vorm van therapie te gaan (*A tablet-based prompted voiding intervention*). Dit bleek te gaan over een studie waarin een nieuwe methode werd getest bij drie zorgvragers. Het doel van de studie was om te bekijken of een dergelijke methode gebruikt zou kunnen worden, niet om aan te tonen dat deze beter is dan een andere methode. De bewijslast van deze studie is te laag om op te nemen in de deze richtlijn, omdat het studiedesign niet geschikt is om de effectiviteit van een interventie aan te tonen.

Uiteindelijk zijn er geen aanvullende relevante wetenschappelijke artikelen gevonden.



Figuur 5. Schematische weergave selectieproces quick scan literatuur.

Expert opinion

Er is weinig (nieuwe) literatuur beschikbaar over de werkzaamheid van niet-medicamenteuze interventies bij thuiswonende ouderen, daarom is een groot deel van de aanbevelingen gebaseerd op de kennis en meningen van de werkgroep. Met de werkgroep is gediscussieerd over goede incontinentiezorg tijdens vergaderingen en in schriftelijke rondes. Tijdens deze discussies is expliciet besproken of de aanbevelingen en overwegingen uit internationale richtlijnen ook toepasbaar zijn in de Nederlandse setting. Daarbij werd ook rekening gehouden met de doelgroep ouderen en of het toepasbaar is bij zowel mannen als vrouwen. Daarnaast moet ook rekening worden gehouden met de thuissituatie. Sommige interventies zijn getest in instellingen en daarmee niet 1-op-1 toepasbaar in de thuissituatie. Interventies die niet in de thuissituatie uitgevoegd kunnen worden, bijvoorbeeld doordat er 24-uurs zorg voor nodig is, zijn niet opgenomen in aanbevelingen.

Bij het thema interventies is ook aan de werkgroep gevraagd om samenhang te zoeken tussen de verschillende interventies binnen deze uitgangsvraag. Elke interventie vraagt een andere inspanning van de verzorgende of verpleegkundige, maar ook van de cliënt. De werkgroep heeft geprobeerd een globale volgorde van de interventies aan te geven. Daarbij is ook rekening gehouden met het inzetten van medicamenteuze interventies. Medicatie geeft over het algemeen meer bijwerkingen en zou daarom na niet-medicamenteuze interventies geadviseerd moeten worden. Daarom komen in de richtlijn ook eerst de niet-medicamenteuze interventies aan bod, en daarna de medicamenteuze.

Ook zijn de algemene aanbevelingen, zoals rekening houden met de wensen van zorgvragers, zo veel mogelijk gelijk voor urine en fecale incontinentie, zodat verzorgende en verpleegkundige voor deze twee vormen van incontinentie zoveel mogelijk dezelfde werkwijze kunnen aanhouden.

Update tekst

De tekst van de oude richtlijn is opgesteld in 2008 en behoefde een update in stijl en opmaak. De tekst is omgezet naar het nieuwe V&VN template voor richtlijnen. Waarbij koppen zijn aangepast en tekst ingekort, waar nodig.

Daarnaast zijn de aanbevelingen uit de geüpdatete internationale richtlijnen toegevoegd. Aangezien de internationale richtlijnen relatief weinig veranderingen hebben ondergaan is er gekozen om de oude richtlijntekst over te nemen en alleen daar waar grote wijzigingen zijn de tekst aan te passen.

In de oude richtlijn was weinig aandacht voor ouderen en de wijkverpleging. Aanbevelingen over toiletgang gingen soms uit van ouderen die verblijven in een instelling. In de thuissituatie is er niet de hele dag verzorging en verpleging aanwezig. Daarom is bij het updaten van de tekst gelet op de toepasbaarheid in de thuissituatie zonder continue zorg.

Ook de overwegingen zijn opnieuw bekeken en aangevuld of aangepast. Dit is gedaan met input uit de nieuwe richtlijnen en input vanuit de werkgroep. In de oude richtlijntekst werden niet alle onderdelen van de huidige invulling van de overwegingen besproken.

Bij elke werkgroep-vergadering was minstens één patiëntvertegenwoordiger aanwezig. In de nieuwe richtlijntekst is meer aandacht voor wensen en behoeften van patiënten en voor samenwerking met andere disciplines en mantelzorgers. Door hier meer aandacht aan te besteden hoopt de werkgroep dat de richtlijn meer aansluit bij de huidige tijd.

Commentaarfase en aanpassingen

Naar aanleiding van de commentaarfase zijn de volgende punten aangepast:

- Enkele tekstuele wijzigingen zijn gemaakt in de aanbevelingen en de moduletekst ten behoeve van de leesbaarheid.
- In aanbeveling 3 over coping strategieën was het niet duidelijk dat de wijkverpleging alleen adviezen geeft over bespreekbaar maken bij familie. Sommige lezers dachten dat de wijkverpleging ook met de familie moest praten. De aanbeveling is aangepast.
- De aanbevelingen over vragenlijsten zijn uitgebreid met een kleine tabel met het doel van elke vragenlijst.
- Risico's op een beschadigde huid zijn toegevoegd in de aanbevelingen en de overwegingen.

Bijlage

Tabel 28. Niet na richtlijnen verschenen

Pub jaar	Referentie
2008	Aslan, E., N. Komurcu, N. K. Beji and O. Yalcin (2008). "Bladder training and Kegel exercises for women with urinary complaints living in a rest home." Gerontology 54(4): 224-231.
2008	Hoşcan, M. B., C. Dilmen, H. Perk, S. Soyupek, A. Armağan, O. Tükel and M. Ekinci (2008). "Extracorporeal magnetic innervation for the treatment of stress urinary incontinence: results of two-year follow-up." Urol Int 81(2): 167-172.
2008	Kumari, S., V. Jain, A. K. Mandal and A. Singh (2008). "Behavioral therapy for urinary incontinence in India." Int J Gynaecol Obstet 103(2): 125-130.
2008	Ng, S. C., T. L. Lin, S. J. Chang, H. L. Tai, S. W. Hu and G. D. Chen (2008). "Nursing intervention to enhance efficacy of home practice of pelvic floor muscle exercises in treating mixed urinary incontinence." Int Urogynecol J Pelvic Floor Dysfunct 19(5): 637-642.
2009	Tsai, Y. C. and C. H. Liu (2009). "The effectiveness of pelvic floor exercises, digital vaginal palpation and interpersonal support on stress urinary incontinence: an experimental study." Int J Nurs Stud 46(9): 1181-1186.
2010	Schreiner, L., T. G. dos Santos, M. R. Knorst and I. G. da Silva Filho (2010). "Randomized trial of transcutaneous tibial nerve stimulation to treat urge urinary incontinence in older women." Int Urogynecol J 21(9): 1065-1070.
2010	Simard, C. and L. M. Tu (2010). "Long-term efficacy of pelvic floor muscle rehabilitation for older women with urinary incontinence." J Obstet Gynaecol Can 32(12): 1163-1166.
2010	Tannenbaum, C., R. Drali, J. Holroyd-Leduc and L. Richard (2010). "Lessons learned: impact of a continence promotion activity for older community-dwelling women." Neurourol Urodyn 29(4): 540-544.
2011	Kim, H., H. Yoshida and T. Suzuki (2011). "The effects of multidimensional exercise on functional decline, urinary incontinence, and fear of falling in community-dwelling elderly women with multiple symptoms of geriatric syndrome: a randomized controlled and 6-month follow-up trial." Arch Gerontol Geriatr 52(1): 99-105.
2011	Santacreu, M. and R. Fernández-Ballesteros (2011). "Evaluation of a behavioral treatment for female urinary incontinence." Clin Interv Aging 6: 133-139.
2012	Mao, W., M. Jiang, W. Chen, J. Du and Q. Xiao (2023). "The effect of using mobile phone applications for intelligent pelvic floor rehabilitation on elderly female patients with stress urinary incontinence." Technol Health Care.
2012	Tak, E. C., A. van Hespen, P. van Dommelen and M. Hopman-Rock (2012). "Does improved functional performance help to reduce urinary incontinence in institutionalized older women? A multicenter randomized clinical trial." BMC Geriatr 12: 51.
2012	Vinsnes, A. G., J. L. Helbostad, S. Nyrønning, G. E. Harkless, R. Granbo and A. Seim (2012). "Effect of physical training on urinary incontinence: a randomized parallel group trial in nursing homes." Clin Interv Aging 7: 45-50.

Pub jaar	Referentie
2012	Wallis, M. C., E. A. Davies, L. Thalib and S. Griffiths (2012). "Pelvic static magnetic stimulation to control urinary incontinence in older women: a randomized controlled trial." Clin Med Res 10(1): 7-14.
2013	Betschart, C., S. E. Mol, B. Lütolf-Keller, D. Fink, D. Perucchini and D. Scheiner (2013). "Pelvic floor muscle training for urinary incontinence: a comparison of outcomes in premenopausal versus postmenopausal women." Female Pelvic Med Reconstr Surg 19(4): 219-224.
2013	Chêne, G., A. Mansoor, B. Jacquetin, G. Mellier, S. Douvier, F. Sergent, Y. Aubard and P. Seffert (2013). "Female urinary incontinence and intravaginal electrical stimulation: an observational prospective study." Eur J Obstet Gynecol Reprod Biol 170(1): 275-280.
2013	Dugan, S. A., M. D. Lavender, J. Hebert-Beirne and L. Brubaker (2013). "A pelvic floor fitness program for older women with urinary symptoms: a feasibility study." Pm r 5(8): 672-676.
2013	Pereira, V. S., M. V. de Melo, G. N. Correia and P. Driusso (2013). "Long-term effects of pelvic floor muscle training with vaginal cone in post-menopausal women with urinary incontinence: a randomized controlled trial." Neurourol Urodyn 32(1): 48-52.
2013	Resnick, N. M., S. Perera, S. Tadic, L. Organist, M. A. Riley, W. Schaefer and D. Griffiths (2013). "What predicts and what mediates the response of urge urinary incontinence to biofeedback?" Neurourol Urodyn 32(5): 408-415.
2013	Starr, J. A., E. Z. Drobnis, S. Lenger, J. Parrot, B. Barrier and R. Foster (2013). "Outcomes of a comprehensive nonsurgical approach to pelvic floor rehabilitation for urinary symptoms, defecatory dysfunction, and pelvic pain." Female Pelvic Med Reconstr Surg 19(5): 260-265.
2014	Costantini, E., M. Lazzeri, V. Bini, A. Zucchi, E. Scarponi and M. Porena (2014). "Managing female urinary incontinence: a regional prospective analysis of cost-utility ratios (curs) and effectiveness." Arch Ital Urol Androl 86(2): 112-117.
2014	Kargar Jahromi, M., M. Talebizadeh and M. Mirzaei (2014). "The effect of pelvic muscle exercises on urinary incontinency and self-esteem of elderly females with stress urinary incontinency, 2013." Glob J Health Sci 7(2): 71-79.
2014	Yu, P., D. Hailey, R. Fleming and V. Traynor (2014). "An exploration of the effects of introducing a telemonitoring system for continence assessment in a nursing home." J Clin Nurs 23(21-22): 3069-3076.
2015	Alves, F. K., C. Riccetto, D. B. Adami, J. Marques, L. C. Pereira, P. Palma and S. Botelho (2015). "A pelvic floor muscle training program in postmenopausal women: A randomized controlled trial." Maturitas 81(2): 300-305.
2015	Elliott, V., E. D. de Bruin and C. Dumoulin (2015). "Virtual reality rehabilitation as a treatment approach for older women with mixed urinary incontinence: a feasibility study." Neurourol Urodyn 34(3): 236-243.
2015	Lacombe Ade, C., V. M. Riccobene and L. A. Nogueira (2015). "Effectiveness of a program of therapeutic exercises on the quality of life and lumbar disability in women with Stress Urinary Incontinence." J Bodyw Mov Ther 19(1): 82-88.
2015	Leong, B. S. and N. W. Mok (2015). "Effectiveness of a new standardised Urinary Continence Physiotherapy Programme for community-dwelling older women in Hong Kong." Hong Kong Med J 21(1): 30-37.
2015	Tenfelde, S., D. Tell, T. N. Thomas and K. Kenton (2015). "Quality of life in women who use pessaries for longer than 12 months." Female Pelvic Med Reconstr Surg 21(3): 146-149.
2015	Wu, S. P., T. S. Lo, L. B. Pue, E. F. Cortes, M. H. Lu, A. M. Al-Kharabsheh and Y. H. Lin (2015). "Outcome after conservative management for mixed urinary incontinence." J Obstet Gynaecol Res 41(2): 269-276.
2015	Zarowitz, B. J., C. Allen, T. O'Shea, E. Tangalos, T. Berner and J. G. Ouslander (2015). "Clinical Burden and Nonpharmacologic Management of Nursing Facility Residents with Overactive Bladder and/or Urinary Incontinence." Consult Pharm 30(9): 533-542.

Pub jaar	Referentie
2016	Engberg, S. and S. M. Sereika (2016). "Effectiveness of Pelvic Floor Muscle Training for Urinary Incontinence: Comparison Within and Between Nonhomebound and Homebound Older Adults." J Wound Ostomy Continence Nurs 43(3): 291-300.
2016	Fernández-Cuadros, M. E., J. Nieto-Blasco, A. Geanini-Yagüez, D. Ciprián-Nieto, B. Padilla-Fernández and M. F. Lorenzo-Gómez (2016). "Male Urinary Incontinence: Associated Risk Factors and Electromyography Biofeedback Results in Quality of Life." Am J Mens Health 10(6): Np127-np135.
2016	Solberg, M., T. Alræk, I. Mdala and A. Klovning (2016). "A pilot study on the use of acupuncture or pelvic floor muscle training for mixed urinary incontinence." Acupunct Med 34(1): 7-13.
2017	Lai, C. K. Y. and X. Wan (2017). "Using Prompted Voiding to Manage Urinary Incontinence in Nursing Homes: Can It Be Sustained?" J Am Med Dir Assoc 18(6): 509-514.
2017	Rosenberg, K. (2017). "Prompted Voiding Offers Long-Term Benefits to Nursing Home Residents." Am J Nurs 117(11): 61.
2017	Sampselle, C. M., D. K. Newman, J. M. Miller, K. Kirk, M. A. DiCamillo, T. H. Wagner, T. E. Raghunathan and A. C. Diokno (2017). "A Randomized Controlled Trial to Compare 2 Scalable Interventions for Lower Urinary Tract Symptom Prevention: Main Outcomes of the TULIP Study." J Urol 197(6): 1480-1486.
2017	Talley, K. M. C., J. F. Wyman, U. Bronas, B. J. Olson-Kellogg and T. C. McCarthy (2017). "Defeating Urinary Incontinence with Exercise Training: Results of a Pilot Study in Frail Older Women." J Am Geriatr Soc 65(6): 1321-1327.
2018	Diokno, A. C., D. K. Newman, L. K. Low, T. L. Griebling, M. E. Maddens, P. S. Goode, T. E. Raghunathan, L. L. Subak, C. M. Sampselle, J. A. Boura, A. E. Robinson, D. McIntyre and K. L. Burgio (2018). "Effect of Group-Administered Behavioral Treatment on Urinary Incontinence in Older Women: A Randomized Clinical Trial." JAMA Intern Med 178(10): 1333-1341.
2018	Radzimińska, A., M. Weber-Rajek, A. Strączyńska, M. Podhorecka, M. Kozakiewicz, K. Kędziora-Kornatowska and A. Goch (2018). "The impact of pelvic floor muscle training on the myostatin concentration and severity of urinary incontinence in elderly women with stress urinary incontinence - a pilot study." Clin Interv Aging 13: 1893-1898.
2018	Sirls, E. R., K. A. Killinger, J. A. Boura and K. M. Peters (2018). "Percutaneous Tibial Nerve Stimulation in the Office Setting: Real-world Experience of Over 100 Patients." Urology 113: 34-39.
2018	Vadalà, M., B. Palmieri, A. Malagoli and C. Laurino (2018). "High-power Magnetotherapy: A New Weapon in Urinary Incontinence?" Low Urin Tract Symptoms 10(3): 266-270.
2019	Pintos-Díaz, M. Z., P. Parás-Bravo, C. Alonso-Blanco, C. Fernández-de-Las-Peñas, M. Paz-Zulueta, M. Cueli-Arce and D. Palacios-Ceña (2019). "The Use of Disposable Tampons as Visual Biofeedback in Pelvic Floor Muscle Training." Int J Environ Res Public Health 16(12).
2019	Virtuoso, J. F., E. C. Menezes and G. Z. Mazo (2019). "Effect of Weight Training with Pelvic Floor Muscle Training in Elderly Women with Urinary Incontinence." Res Q Exerc Sport 90(2): 141-150.
2019	Weber-Rajek, M., A. Radzimińska, A. Strączyńska, K. Strojek, Z. Piekorz, M. Kozakiewicz and H. Styczyńska (2019). "A Randomized-Controlled Trial Pilot Study Examining the Effect of Pelvic Floor Muscle Training on the Irisin Concentration in Overweight or Obese Elderly Women with Stress Urinary Incontinence." Biomed Res Int 2019: 7356187.
2019	Brown, H. W., E. J. Braun, M. E. Wise, S. Myers, Z. Li, E. Sampene, S. M. Jansen, D. P. Moberg, J. E. Mahoney and R. G. Rogers (2019). "Small-Group, Community-Member Intervention for Urinary and Bowel Incontinence: A Randomized Controlled Trial." Obstet Gynecol 134(3): 600-610.
2019	Felsted, K. F. and K. P. Supiano (2019). "Mindfulness-Based Stress Reduction Versus a Health Enhancement Program in the Treatment of Urge Urinary Incontinence in Older Adult Women: A Randomized Controlled Feasibility Study." Res Gerontol Nurs 12(6): 285-297.

Pub jaar	Referentie
2019	Tannenbaum, C., X. Fritel, A. Halme, E. van den Heuvel, J. Jutai and A. Wagg (2019). "Long-term effect of community-based continence promotion on urinary symptoms, falls and healthy active life expectancy among older women: cluster randomised trial." Age Ageing 48(4): 526-532.

Tabel 29. Full tekst beoordeelde artikelen

Pub jaar	Referentie	Opmerking *Uit abstract referentie*	Relevant voor update Ja/nee
Bekkenbodemspiertraining			
2021	Bech, S. R., D. Villadsen, H. H. Laursen, A. Toft, H. S. Reinau, T. H. Raasted, K. W. Christensen, L. H. Corfitzen and S. W. McPhee Christensen (2021). "The effect of group or individualised **pelvic floor exercises** with or without ultrasonography guidance for urinary incontinence in elderly women - A pilot study." J Bodyw Mov Ther 28: 34-41.		Nee
2021	Booth, J., L. Aucott, S. Cotton, B. Davis, L. Fenocchi, C. Goodman, S. Hagen, D. Harari, M. Lawrence, A. Lowndes, L. Macaulay, G. MacLennan, H. Mason, D. McClurg, J. Norrie, C. Norton, C. O'Dolan, D. Skelton, C. Surr and S. Treweek (2021). "**Tibial nerve stimulation** compared with sham to reduce incontinence in care home residents: ELECTRIC RCT." Health Technol Assess 25(41): 1-110.		Nee
2021	Cacciari, L. P., M. Morin, M. H. Mayrand, M. Tousignant, M. Abrahamowicz and C. Dumoulin (2021). "Pelvic floor morphometrical and functional changes immediately after **pelvic floor muscle training** and at 1-year follow-up, in older incontinent women." Neurourol Urodyn 40(1): 245-255.		Nee
2022	Kannan, P., W. H. Hsu, W. T. Suen, L. M. Chan, A. Assor and C. M. Ho (2022). "Yoga and Pilates compared to **pelvic floor muscle training** for urinary incontinence in elderly women: A randomised controlled pilot trial." Complement Ther Clin Pract 46: 101502.		Nee
2022	Yao, H., X. Zhang, F. Sun, G. Tang, J. Wu and Z. Zhou (2022). "The efficacy of **intravaginal electrical stimulation** (IVES) in treating female with urinary incontinence symptom from meta-analysis of nine randomized controlled trials." Front Neurol 13: 933679.		Nee
2023	Dominguez, A. P., P. G. Isaza, S. N. Pantoja and I. Fusco (2023). "Role of top **flat magnetic stimulation** for urinary incontinence as a debilitating condition of pelvic floor dysfunction: an observational evaluation of Latin American population." World J Urol 41(1): 173-177.		Nee
2022	Parker-Autry, C., R. Neiberg, X. I. Leng, C. A. Matthews, C. Dumoulin, G. Kuchel and S. B. Kritchevsky (2022). "Examining the Role of **Nonsurgical Therapy** in the Treatment of Geriatric Urinary Incontinence." Obstet Gynecol 140(2): 243-251.	Individualized pelvic floor muscle training prescriptions with behavioral management strategies to reduce	Nee , bekkenbodemspier training

		incontinence episodes were provided for 12 weeks	
2023	Keyser, L. E., J. L. McKinney, S. J. Pulliam and M. M. Weinstein (2023). "A **digital health program** for treatment of urinary incontinence: retrospective review of real-world user data." Int Urogynecol J 34(5): 1083-1089.	retrospective cohort study of real-world data from users of a pDTx designed to guide pelvic floor muscle training (PFMT) - Mean age was 51.2 ± 11.5 years (range 22–84	Nee, niet primair ouderen, ook bekkenbodemspier training
Andere interventies?			
2020	Davis, N. J., P. C. Clark, T. M. Johnson, 2nd and J. F. Wyman (2020). "Feasibility of Tele-Prompt: A **tablet-based prompted voiding intervention** to support informal caregivers of older adults with urinary incontinence." Geriatr Nurs 41(4): 411-420.	The purpose of this feasibility study was twofold. Firstly, to explore the feasibility of an innovative, technology-delivered, prompted-voiding and skill-building intervention to support the informal caregivers of functionally-limited older adults	Nee. Slechts 3 paren onderzocht, feasibility studie

Verantwoording Uitgangsvraag 3b – Medicamenteuze behandelinterventies voor urine-incontinentie

Literatuursearch en selectie

Er is in maart 2023 systematisch literatuuronderzoek uitgevoerd in drie verschillende databases: PubMed, CINAHL en EMBASE. Volgens de AQUA-leidraad is uitgangsvraag 3 vertaald in een PICO vraag, die het probleem of patiënt/populatie (P), de Interventie (I), de vergelijking/comparison (C) en de gewenste uitkomstmaat/outcome (O) beschrijven. Ook werd het type onderzoek vastgesteld waarmee de vraag moet worden beantwoord (vergelijkende onderzoek, observationeel onderzoek en SLRs).

Tabel 30. PICO medicamenteuze interventies van UI bij ouderen.

P:	Ouderen, gemiddelde leeftijd in populatie ≥60 j
I:	Medicamenteuze behandelinterventies
C:	Elke vergelijking (Ander soort behandeling/geen behandeling)
O:	Relevante uitkomstmaten: - Ervaren kwaliteit van leven door de zorgvrager - Ervaren gezondheid, verbetering door de zorgvrager - Ervaren hinder door de zorgvrager als gevolg van urine-continentieproblemen - Symptoomscores (incontinence impact questionnaire; urogential distress inventory)

De PICO-vraag is omgezet in zoektermen die gecombineerd zijn tot een zoekstrategie waarmee de gewenste literatuur geïdentificeerd is (zie Tabel 31).

Tabel 31. Zoekstrategie per informatiedatabase.

Database	Zoekstrategie
PUBMED	"Urinary Incontinence"[Mesh] OR “urinary incontinence”[tiab] OR “urine incontinence”[tiab] OR "overflow incontinence"[tiab] OR "urge incontinence"[tiab] OR "stress incontinence"[tiab] OR "mixed incontinence"[tiab] OR "functional incontinence"[tiab] OR "detrusor overactivity"[tiab] OR "urgency"[tiab] OR "nocturia"[tiab] OR "bladder overactivity"[tiab] OR "bladder hyperactivity"[tiab] OR “overactive bladder”[tiab] OR "sensory urge incontinence"[tiab] OR "detrusor hyperreflexia"[tiab] OR "neurogenic incontinence"[tiab] AND "Frail Elderly"[Mesh] OR "Aged, 80 and over"[Mesh] OR frail*[tiab] OR vulnerable[tiab] OR "low functioning"[tiab] OR "functional decline"[tiab] OR aging[tiab] OR ageing[tiab] OR elder*[tiab] OR old[tiab] OR older[tiab] OR geriatric*[tiab] OR "older people"[tiab] OR "community dwelling elderly"[tiab] OR "care home"[tiab] OR “community care”[tiab] OR “nursing care”[tiab] OR nurse[ad] OR nursing[ad] AND "Drug Therapy"[Mesh] OR "pharmaceutical preparations"[Mesh] OR "drug treatment"[Title/Abstract:~3] OR “drug therapies”[Title/Abstract:~3] OR “drug therapy”[Title/Abstract:~3] OR “Pharmacologic therapy”[tiab] OR medication*[tiab] OR antimuscarinic*[tiab] OR anticholinergic*[tiab] OR sympathomimetic[tiab] OR Estrogen[tiab] OR desmopressin[tiab] OR amitriptyline[tiab] OR flavoxate[tiab] OR mirabegron[tiab] OR solifenacin[tiab] OR “β3-adrenoceptor agonist”[tiab] OR “β-3 agonists”[tiab] AND Systematic review[pt] OR systematic review[tiab] OR meta-analysis[pt] OR meta-analysis[tiab] OR meta-analyses[tiab] OR meta analysis[tiab] OR meta analyses[tiab] OR metaanalysis[tiab] OR metaanalyses[tiab] OR randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled[tiab] OR placebo*[tiab] OR trial[tiab] OR intervention[tiab] OR "Cross-Over Studies"[Mesh] OR "Double-Blind Method"[Mesh] OR "Prospective Studies"[Mesh] OR "Follow-up Studies"[Mesh] OR "Cohort Studies"[Mesh] OR crossover[tiab] OR cross-over[tiab] OR double-blind[tiab] OR doubleblind[tiab] OR single-blind[tiab] OR singleblind[tiab] OR cohort*[tiab] OR prospective[tiab] OR longitudinal[tiab] OR observational[tiab] OR follow-up[tiab] OR followup[tiab] OR effectiveness[tiab] OR safety[tiab] OR “clinical review”[tiab] OR “literature review”[tiab]
EMBASE	‘Urine Incontinence’/exp OR ‘urinary incontinence’:ti,ab OR 'overflow incontinence':ti,ab OR 'urge incontinence':ti,ab OR 'stress incontinence':ti,ab OR 'mixed incontinence':ti,ab OR 'functional incontinence':ti,ab OR 'detrusor overactivity':ti,ab OR urgency:ti,ab OR nocturia:ti,ab OR 'bladder overactivity':ti,ab OR 'bladder hyperactivity':ti,ab OR 'sensory urge incontinence':ti,ab OR 'detrusor hyperreflexia':ti,ab OR 'neurogenic incontinence':ti,ab AND ‘Frail Elderly’/exp OR ‘Very elderly’/exp OR frail*:ti,ab OR 'vulnerable’:ti,ab OR ‘low functioning’:ti,ab OR 'functional decline':ti,ab OR aging:ti,ab OR ageing:ti,ab OR elder*:ti,ab OR old:ti,ab OR older:ti,ab OR geriatric*:ti,ab OR 'older people':ti,ab OR 'community dwelling elderly':ti,ab OR 'care home':ti,ab OR 'community care':ti,ab OR 'nursing care':ti,ab OR nurse:ad OR nursing:ad AND ‘drug’/exp OR ‘drug therapy’/exp OR medic*:ti,ab OR (drug NEAR/3 treatment):ti,ab OR (drug NEAR/3 therapies):ti,ab OR (drug NEAR/3 therapy):ti,ab OR ‘pharmacologic therapy’ OR antimuscarinic*:ti,ab OR anticholinergic*:ti,ab OR sympathomimetic:ti,ab OR Estrogen:ti,ab OR desmopressin:ti,ab OR amitriptyline:ti,ab OR flavoxate:ti,ab OR mirabegron:ti,ab OR solifenacin:ti,ab OR ‘β3-adrenoceptor agonist’:ti,ab OR ‘β-3 agonists’:ti,ab AND ‘Systematic review’/exp OR ‘systematic review’:ti,ab OR ‘meta analysis’/exp OR meta-analysis:ti,ab OR meta-analyses:ti,ab OR 'meta analysis':ti,ab OR 'meta analyses':ti,ab OR metaanalysis:ti,ab OR metaanalyses:ti,ab OR term:it OR term:it OR randomized:ti,ab OR randomised:ti,ab OR RCT:ti,ab OR controlled:ti,ab OR placebo*:ti,ab OR trial:ti,ab OR intervention:ti,ab OR 'Cross-Over Studies'/exp OR 'Double-Blind Method'/exp OR 'Prospective Studies'/exp OR 'Follow-up Studies'/exp OR 'Cohort Studies'/exp OR crossover:ti,ab OR cross-over:ti,ab OR double-blind:ti,ab OR doubleblind:ti,ab OR single-blind:ti,ab OR singleblind:ti,ab OR cohort*:ti,ab OR prospective:ti,ab OR longitudinal:ti,ab OR observational:ti,ab OR follow-up:ti,ab OR followup:ti,ab OR effectiveness:ti,ab OR safety:ti,ab OR ‘clinical review’:ti,ab OR ‘literature review’:ti,ab
CINAHL	TI ("overflow incontinence" OR "urge incontinence" OR "stress incontinence" OR "mixed incontinence" OR "functional incontinence" OR "detrusor overactivity" OR "urgency" OR "nocturia" OR "bladder overactivity" OR "bladder hyperactivity" OR “overactive bladder” OR "sensory urge incontinence" OR "detrusor hyperreflexia" OR "neurogenic incontinence") OR AB ("overflow incontinence" OR "urge incontinence" OR "stress incontinence" OR "mixed incontinence" OR "functional incontinence" OR "detrusor overactivity" OR "urgency" OR "nocturia" OR "bladder overactivity" OR "bladder hyperactivity" OR “overactive bladder” OR "sensory urge incontinence" OR "detrusor hyperreflexia" OR "neurogenic incontinence") OR MH "Urinary Incontinence" AND TI (Frail* OR vulnerable OR "low functioning" OR "functional decline" OR aging OR ageing OR elder* OR old OR older OR geriatric* OR "older people" OR "community dwelling elderly" OR "care home" OR “community care” OR “nursing care”) OR AB (Frail* OR vulnerable OR "low functioning" OR "functional decline" OR aging OR ageing OR elder* OR old OR older OR geriatric* OR "older people" OR "community dwelling elderly" OR "care home" OR “community care” OR “nursing care”) OR MH ("Frail Elderly" OR "Aged, 80 and over") OR AF ("nurse" OR "nursing") ANDTI ("drug treatment" OR “drug therapies” OR “drug therapy” OR “Pharmacologic therapy” OR medication* OR antimuscarinic* OR

	anticholinergic* OR "sympathomimetic" OR "Estrogen" OR "desmopressin" OR "amitriptyline" OR "flavoxate" OR "mirabegron" OR "solifenacin" OR “β3-adrenoceptor agonist” OR “β-3 agonists”) OR AB ("drug treatment" OR “drug therapies” OR “drug therapy” OR “Pharmacologic therapy” OR medication* OR antimuscarinic* OR anticholinergic* OR "sympathomimetic" OR "Estrogen" OR "desmopressin" OR "amitriptyline" OR "flavoxate" OR "mirabegron" OR "solifenacin" OR “β3-adrenoceptor agonist” OR “β-3 agonists”) OR MH ("Drug Therapy" OR "pharmaceutical preparations") AND TI ("Systematic review" OR "meta-analysis" OR "meta-analyses" OR "meta analysis" OR "meta analyses" OR "metaanalysis" OR "metaanalyses" OR "randomized" OR "randomised" OR "RCT" OR "controlled" OR placebo* OR "trial" OR "intervention" OR "crossover" OR "cross-over" OR "double-blind" OR "doubleblind" OR "single-blind" OR "singleblind" OR cohort* OR "prospective" OR "longitudinal" OR "observational" OR "follow-up" OR "followup" OR "effectiveness" OR "safety" OR “clinical review” OR “literature review”) OR AB ("Systematic review" OR "meta-analysis" OR "meta-analyses" OR "meta analysis" OR "meta analyses" OR "metaanalysis" OR "metaanalyses" OR "randomized" OR "randomised" OR "RCT" OR "controlled" OR placebo* OR "trial" OR "intervention" OR "crossover" OR "cross-over" OR "double-blind" OR "doubleblind" OR "single-blind" OR "singleblind" OR cohort* OR "prospective" OR "longitudinal" OR "observational" OR "follow-up" OR "followup" OR "effectiveness" OR "safety" OR “clinical review” OR “literature review”) OR MH ("Cross-Over Studies" OR "Double-Blind Method" OR "Prospective Studies" OR "Follow-up Studies" OR "Cohort Studies") OR PT ("Systematic review" OR "meta-analysis" OR "randomized controlled trial" OR "controlled clinical trial")

Inclusie-en exclusie criteria

Tabel 32 beschrijft de inclusie -en exclusiecriteria die zijn gehanteerd voor de selectie van relevante studies.

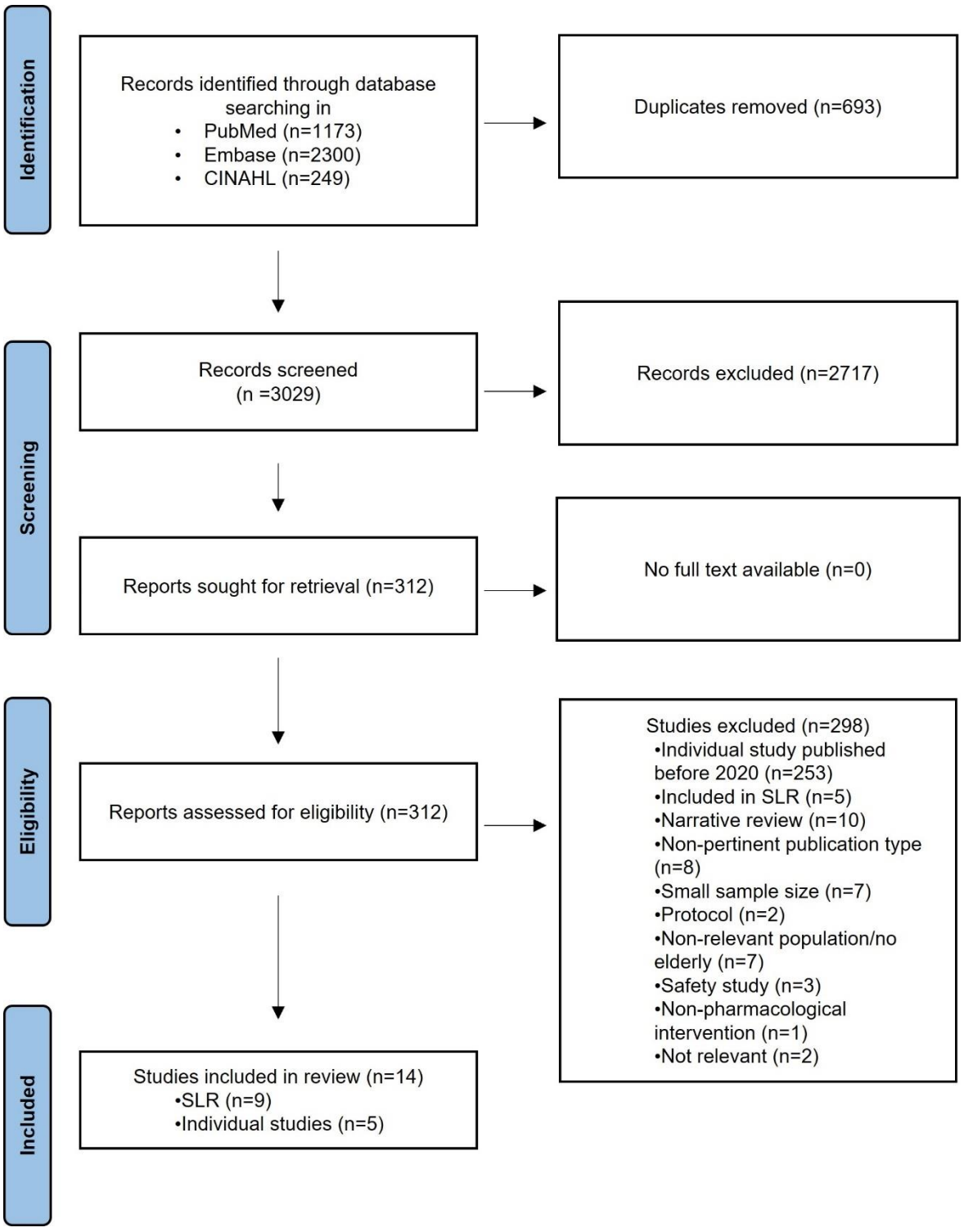
Tabel 32. In- en exclusiecriteria.

	Inclusie	Exclusie
Publicatieperiode	Vanaf 2008	Gepubliceerd vóór 2008
Scope	Wereldwijd	/
Taal	Engels, Nederlands	Overige talen
Studiepopulatie	Ouderen Gemiddelde leeftijd in onderzoekspopulatie ≥60 jaar	- Zwangere vrouwen - Vrouwen tijdens en voor de menopauze - Kinderen, adolescenten - Dierstudies - Mensen die al langer incontinentie zijn door een degeneratieve ziekte (MS, ALS) - Mensen met een verstandelijke beperking - Patiënten die door een andere aandoening incontinentie zijn geworden
	Verpleegkundigen en verzorgenden werkzaam in de wijk	Professionals niet werkzaam in de wijk
Focus van de studie	- Medicamenteuze behandeling	- Chirurgische ingrepen - Preventie - Diagnostiek - Andere niet medicamenteuze interventies
Studie uitkomsten	- Ervaren Kwaliteit van leven door de zorgvrager - Ervaren gezondheid door de zorgvrager - Ervaren hinder door de zorgvrager als gevolg van urine-continentieproblemen - Ervaren verbetering door de zorgvrager - Symptoomscores (incontinence impact questionnaire; urogential distress inventory) - Grootte van de zorgvraag	
Publicatietype	Peer-reviewed artikelen	- Boek - Letter to the editor - Commentaar - Editorial - Congres abstract
Studiedesign	- Gerandomiseerde gecontroleerde studies (RCT) - Observationele studies	- Case report - Case series - Narratieve reviews

	- Literatuurreview - Meta-analyse	

Selectie van artikelen: De selectie van titels/abstracts werd 20% dubbel uitgevoerd met behulp van de software van Rayyan. Verdere selectie van de volledige tekst werd door één onderzoeker volledig gedaan, een andere onderzoeker controleerde de geëxcludeerde artikelen. Twijfelgevallen werden samen besproken tot een consensus was bereikt. Als de inclusiecriteria niet goed toepasbaar waren, werd het artikel voorgelegd aan de werkgroep. De uitkomsten van de selectie van de volledige tekst werden in Excel geregistreerd. Voor de geëxcludeerde artikelen werd de reden van exclusie gegeven. De lijst met geëxcludeerde artikelen werd voorgelegd aan de werkgroep ter controle.

In de afbeelding hieronder wordt de selectie van de literatuur schematisch weergegeven. Uiteindelijk zijn er 14 studies geïncludeerd (9 systematische reviews en 5 individuele studies) die (deels) antwoord geven op de uitkomstvragen. Tabel 33 en Tabel 34 geven de details van de geëxcludeerde studies weer



Figuur 6. Flow-chart van de SLR-uitgangsvraag 3b

Tabel 33. Reden voor exclusive voor systematische literatuurreviews (N=4)

Reden voor exclusie	Volledige referentie
Not relevant (n=1)	Chapple, C., M. Oelke, S. A. Kaplan, D. Scholfield, D. Arumi and A. S. Wagg (2015). "Fesoterodine clinical efficacy and safety for the treatment of overactive bladder in relation to patient profiles: a systematic review." Curr Med Res Opin 31(6): 1201-1243.
Protocol (n=1)	Roy, J. C., C. Rousseau, A. Jutel, F. Naudet and G. Robert (2022). "Tolerability of duloxetine in elderly and in non-elderly adults: a protocol of a systematic review and individual participant data meta-analysis of randomized placebo-controlled trials." Systematic Reviews 11(1).
Safety study or adverse events (n=2)	Vouri, S. M., C. D. Kebodeaux, P. M. Stranges and B. F. Teshome (2017). "Adverse events and treatment discontinuations of antimuscarinics for the treatment of overactive bladder in older adults: A systematic review and meta-analysis." Arch Gerontol Geriatr 69: 77-96.
	Yi, W., Y. Yang and J. Yang (2021). "Monotherapy with mirabegron had a better tolerance than the anticholinergic agents on overactive bladder: A systematic review and meta-analysis." Medicine (Baltimore) 100(41): e27469.

Tabel 34. Reden voor exclusie voor individuele studies (n=41) – studies gepubliceerd voor 2020 niet meegenomen in tabel

Reden voor exclusie	Volledige referentie
Included in SLR (n=5)	Chapple, C. R., F. Cruz, L. Cardozo, D. Staskin, S. Herschorn, N. Choudhury, M. Stoelzel, J. Heesakkers and E. Siddiqui (2020). "Safety and Efficacy of Mirabegron: Analysis of a Large Integrated Clinical Trial Database of Patients with Overactive Bladder Receiving Mirabegron, Antimuscarinics, or Placebo." Eur Urol 77(1): 119-128.
	Kaplan, S. A., S. Herschorn, K. T. McVary, D. Staskin, C. Chapple, S. Foley, J. Cambronero Santos, R. M. Kristy, N. Choudhury, J. Hairston and C. R. Schermer (2020). "Efficacy and Safety of Mirabegron versus Placebo Add-On Therapy in Men with Overactive Bladder Symptoms Receiving Tamsulosin for Underlying Benign Prostatic Hyperplasia: A Randomized, Phase 4 Study (PLUS)." J Urol 203(6): 1163-1171.
	Yamanishi, T., K. Kaga, K. Sakata, T. Yokoyama, S. Kageyama, M. Fuse and S. Tokunaga (2020). "A randomized controlled study of the efficacy of tadalafil monotherapy versus combination of tadalafil and mirabegron for the treatment of persistent overactive bladder symptoms in men presenting with lower urinary tract symptoms (CONTACT Study)." Neurourol Urodyn 39(2): 804-812.
	Wagg, A., D. Staskin, E. Engel, S. Herschorn, R. M. Kristy and C. R. Schermer (2020). "Efficacy, safety, and tolerability of mirabegron in patients aged ≥65yr with overactive bladder wet: a phase IV, double-blind, randomised, placebo-controlled study (PILLAR)." Eur Urol 77(2): 211-220.
	Johnson, T. M., P. S. Goode, L. Hammontree, A. D. Markland, C. P. Vaughan, J. G. Ouslander, K. Falk, G. McGwin and K. L. Burgio (2021). "An Exploratory Analysis of Tamsulosin for Overactive Bladder (OAB) in Men With Varying Voiding Symptom Burden." Urology 153: 42-48.
Narrative review (n=10)	Chen, J. L., Y. H. Jiang, C. L. Lee and H. C. Kuo (2020). "Precision medicine in the diagnosis and treatment of male lower urinary tract symptoms suggestive of benign prostatic hyperplasia." Ci Ji Yi Xue Za Zhi 32(1): 5-13.
	Hou, R., Y. Yu and J. Jiang (2021). "PGE2 receptors in detrusor muscle: Drugging the undruggable for urgency." Biochem Pharmacol 184: 114363.
	Kuo, H. C. (2022). "How to choose appropriate medication for overactive bladder: Findings from the largest integrated clinical trial database analysis of mirabegron studies." Tzu Chi Med J 34(1): 23-28.

Reden voor exclusie	Volledige referentie
	Makhani, A., M. Thake and W. Gibson (2020). "Mirabegron in the Treatment of Overactive Bladder: Safety and Efficacy in the Very Elderly Patient." Clin Interv Aging 15: 575-581.
	O'Kane M, Robinson D, Cardozo L, Wagg A, Abrams P.(2022) Mirabegron in the Management of Overactive Bladder Syndrome. Int J Womens Health.16;14:1337-1350.
	Wagg, A. and R. Lee (2021). "Urinary Incontinence in People Living with Cognitive Impairment." Current Geriatrics Reports 10(3): 124-131.
	Wolff, D. T., K. A. Adler, C. S. Weinstein and J. P. Weiss (2021). "Managing Nocturia in Frail Older Adults." Drugs Aging 38(2): 95-109.
	Monti, M., M. Fischetti, G. Santangelo, V. Galli, F. Clemente, A. Giannini, V. Tibaldi, A. Di Pinto, F. Pecorini, G. Perniola, V. Di Donato and P. Benedetti Panici (2020). "Urinary incontinence in women: state of art and medical treatment." Minerva ginecologica.
	Pearlman, A. and K. Kreder (2020). "Evaluation and treatment of urinary incontinence in the aging male." Postgraduate Medicine 132(sup4): 9-17.
	Xiao Yun, L. (2021). "An update on vaginal oestrogen for overactive bladder: reporting the literature." Australian & New Zealand Continence Journal 27(2): 40-46.
Non-pertinent publication (n=8)	Lee, A. (2021). "Take an individualised approach when treating frail, elderly patients with nocturia." Drugs and Therapy Perspectives 37(8): 354-357.
	Marcelissen, T. and K. Rademakers (2020). "Treatment of Elderly Patients with Overactive Bladder: Has Mirabegron Come of Age?" Eur Urol 77(2): 221-222.
	Shaw, C. and A. Wagg (2020). "Overactive Bladder in Frail Older Adults." Drugs Aging 37(8): 559-565.
	Shaw, C. and A. Wagg (2021). "Urinary and faecal incontinence in older adults." Medicine (United Kingdom) 49(1): 44-50.
	Wagg, A. S., S. Herschorn, M. Carlsson, M. Fernet and M. Oelke (2022). "A plain language summary of the likelihood of symptom relief for patients taking fesoterodine for overactive bladder." J Comp Eff Res 11(13): 919-925.
	Yeong, K., J. Santiapillai, B. N. Arumainayagam, P. Murray and S. Tadtayev (2021). "NOCTURIA—AN UNDERAPPRECIATED “SYMPTOM” OF OBSTRUCTIVE SLEEP APNOEA?...British Geriatrics Society Autumn Meeting, November 25-27 2020 (Virtual)." Age & Ageing 50: i1-i1.
	Gleicher, S., E. M. Sebesta, W. S. Reynolds and R. Dmochowski (2022). "Vibegron for the treatment of overactive bladder: a comprehensive update." Expert Opin Pharmacother 23(13): 1479-1484.
	Matsukawa Y, Gotoh M. (2020) Factors contributing to the efficacy of two add-on therapies of fesoterodine or mirabegron to silodosin monotherapy for persistent overactive bladder in men with lower urinary tract symptoms. Int J Urol.27(1):85-6.
Non-pharmacological intervention (n=1)	Funada, S., N. Watanabe, T. Goto, H. Negoro, S. Akamatsu, R. Uozumi, S. Kishimoto, K. Ichioka, T. Segawa, T. A. Furukawa and O. Ogawa (2021). "Clinical feasibility and acceptability of adding cognitive behavioral therapy to pharmacotherapy for drug-resistant overactive bladder in women: A single-arm pilot study." Low Urin Tract Symptoms 13(1): 69-78.
Protocol (n=1)	Sun, Y., Y. Liu, T. Su, J. Sun, Y. Wu and Z. Liu (2020). "Electroacupuncture versus solifenacin for women with urgency-predominant mixed urinary incontinence: a protocol for a three-armed non-inferiority randomized controlled trial." BMC Complement Med Ther 20(1): 18.
Safety and tolerability study (n=1)	Herschorn, S., D. Staskin, C. R. Schermer, R. M. Kristy and A. Wagg (2020). "Safety and Tolerability Results from the PILLAR Study: A Phase IV, Double-Blind, Randomized, Placebo-Controlled Study of Mirabegron in Patients ≥ 65 years with Overactive Bladder-Wet." Drugs Aging 37(9): 665-676.
Small sample size (n=7)	Aksak, A., G. Çakmak and Z. A. Öztürk (2021). "A Prospective Study to Investigate the Effect of Fesoterodine Treatment on Quality of Life, Anxiety, and Depression in Urge-Type Urinary Incontinence." Urol J 19(1): 69-74.
	Chu, C. M., H. Harvie, L. A. Arya and U. U. Andy (2021). "Short-Term Effect of Fesoterodine on Physical Function Relevant to Fall Risk in Older Women With Overactive Bladder." Female Pelvic Med Reconstr Surg 27(12): 759-765.

Reden voor exclusie	Volledige referentie
	Karakus, S., B. Musicki and A. L. Burnett (2022). "Mirabegron improves erectile function in men with overactive bladder and erectile dysfunction: a 12-week pilot study." Int J Impot Res 34(6): 588-592.
	Nakagomi, H., T. Mitsui, H. Shimura, T. Ihara, S. Kira, N. Sawada and M. Takeda (2022). "Mirabegron for overactive bladder in frail patients 80 years or over (HOKUTO study)." BMC Urol 22(1): 40.
	Özcan, C., A. Sancı, M. Beyatlı, S. Bedir and Y. Özgök (2023). "The Efficiency and Safety of Mirabegron Monotherapy for the Treatment of Urge Incontinence in Women Aged >80 Years." Cureus 15(1): e33685.
	Wang, C. C., C. L. Lee, Y. T. Hwang and H. C. Kuo (2021). "Adding mirabegron after intravesical onabotulinumtoxinA injection improves therapeutic effects in patients with refractory overactive bladder." LUTS: Lower Urinary Tract Symptoms 13(4): 440-447.
	Wu, T. H., Y. C. Shen, W. C. Lee, H. J. Wang and Y. C. Chuang (2020). "Effect of mirabegron on erectile function in sexually active men with bothersome overactive bladder symptoms." J Chin Med Assoc 83(1): 55-59.
Non-relevant population/no elderly (n=7)	Trbovich, M., T. Romo, M. Polk, W. Koek, C. Kelly, S. Stowe, S. Kraus and D. Kellogg (2021). "The treatment of neurogenic lower urinary tract dysfunction in persons with spinal cord injury: An open label, pilot study of anticholinergic agent vs. mirabegron to evaluate cognitive impact and efficacy." Spinal Cord Series and Cases 7(1).
	Yamanishi, T., H. Asakura, N. Seki and S. Tokunaga (2021). "Triple Therapy with Tamsulosin, Dutasteride, and Imidafenacin for Benign Prostatic Hyperplasia in Patients with Overactive Bladder Symptoms Refractory to Tamsulosin: Subgroup Analyses of the DIrecT Study." Urol Int 105(9-10): 817-825.
	Palmieri, B., T. Iannitti, J. C. Morales-Medina and M. Vadalà (2020). "Monocentric single-arm study of desmopressin acetate efficacy on nocturnal polyuria in the elderly." Int J Clin Pract 74(11): e13612.
	Chen, S. F. and H. C. Kuo (2019). "Therapeutic efficacy of low-dose (25 mg) mirabegron therapy for patients with mild to moderate overactive bladder symptoms due to central nervous system diseases." Low Urin Tract Symptoms 11(2): O53-o58.
	Malde, S., et al. (2021). "Incidence of Nocturia in Men with Lower Urinary Tract Symptoms Associated with Benign Prostatic Enlargement and Outcomes After Medical Treatment: Results from the Evolution European Association of Urology Research Foundation Prospective Multinational Registry." European Urology Focus 7(1): 178-185.
	Mahapatra, S. K., R. R. Dash, B. Rath and P. S. Hota (2022). "Solifenacin and Mirabegron Monotherapies Versus Combination Therapy in Overactive Bladder: A Prospective Observational Study." Biomedical and Pharmacology Journal 15(1): 491-497.
	Alquraishi, F., S. H. Mohammed and Y. Al-Hakeem (2020). "Oral desmopressin as an add-on therapy for men with benign prostate hyperplasia they suffering from persistent nocturia." Medico-Legal Update 20(1): 667-671.
Not relevant (n=1)	Chapple, C. R., E. Mironska, A. Wagg, I. Milsom, D. C. Diaz, H. Koelbl, D. Pushkar, A. Tubaro, D. De Ridder, E. Chartier-Kastler and L. D. Phillips (2020). "Multicriteria Decision Analysis Applied to the Clinical Use of Pharmacotherapy for Overactive Bladder Symptom Complex." Eur Urol Focus 6(3): 522-530.

Kwaliteitsbeoordeling (risk of bias) van de individuele studies

De SLR zijn beoordeeld met behulp van de AMSTAR-2 tool. De score van de AMSTAR-2 is terug te vinden in de evidence tabellen. De individuele artikelen over interventies zijn beoordeeld met de checklists van JBI. De scores per studie zijn weergegeven in Tabel 35 en Tabel 36.

Tabel 35. Risk of bias of basis van JBI: RCT.

Questions according to JBI	Burgio et a. 2020	Komesu et al. 2020	Yoshida et al. 2020
Was true randomization used for assignment of participants to treatment groups?	YES	YES	YES
Was allocation to treatment groups concealed?	YES	YES	YES
Were treatment groups similar at the baseline?	YES	YES	YES
Were participants blind to treatment assignment?	NO	NO	YES
Were those delivering treatment blind to treatment assignment?	NO	NO	YES
Were outcomes assessors blind to treatment assignment?	YES	YES	YES
Were treatment groups treated identically other than the intervention of interest?	YES	YES	YES
Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	YES	YES	YES
Were participants analyzed in the groups to which they were randomized?	YES	YES	YES
Were outcomes measured in the same way for treatment groups?	YES	YES	YES
Were outcomes measured in a reliable way?	UNCLEAR	UNCLEAR	UNCLEAR
Was appropriate statistical analysis used?	YES	YES	YES
Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for	YES	YES	YES

in the conduct and analysis of the trial?			
Overall appraisal	Poor	Poor	Sufficient

Tabel 36. Risk of bias of basis van JBI: quasi-experimental design.

Questions according to JBI	**Huang et al. (Retrospective)**	**Zachariou et. Al (Prospective)**
Is it clear in the study what is the 'cause' and what is the 'effect' (i.e., there is no confusion about which variable comes first)?	YES	YES
Were the participants included in any comparisons similar?	YES	YES
Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	NO	N/A
Was there a control group?	NO	N/A
Were there multiple measurements of the outcome both pre and post the intervention/exposure?	NO	NO
Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	UNCLEAR	NO
Were the outcomes of participants included in any comparisons measured in the same way?	UNCLEAR	NO
Were outcomes measured in a reliable way?	UNCLEAR	UNCLEAR
Was appropriate statistical analysis used?	UNCLEAR	UNCLEAR
Overall appraisal	Poor	Poor

Beoordeling van de kracht van het wetenschappelijk bewijs

Er is veel heterogeniteit in studiepopulaties en studie-uitkomsten. Daarnaast is er ook veel verschil in de studieopzet en vergelijkt nagenoeg elke studie een andere combinatie van interventies in een andere studiepopulatie. De kracht van bewijs is daarom bepaald op basis de beoordeling van de individuele studies. Individuele studies werden systematisch beoordeeld, op basis van op voorhand opgestelde methodologische kwaliteitscriteria, om zo het risico op vertekende studieresultaten (risk of bias) te kunnen inschatten. De methodologische kwaliteit van de geïncludeerde systematische reviews is beoordeeld met de AMSTAR-checklist waarbij een onderverdeling kan worden gemaakt naar reviews van lage kwaliteit (score 0-4), middelmatige kwaliteit (score 5-8) en hoge kwaliteit (score 9-11). De score van de SLRs is opgenomen in de evidence tabellen. De methodologische kwaliteit van geïncludeerde losse individuele studies (RCTs en observationele studies) is beoordeeld met de formulieren van JBI (RCTs en quasi-experimentele studies). Hierboven zijn de scores van artikelen weergegeven. In de evidence tabellen worden de belangrijkste beperkingen opgesomd.

Commentaarfase en aanpassingen

Naar aanleiding van de commentaarfase zijn de volgende punten aangepast:

- Enkele tekstuele wijzigingen zijn gemaakt in de aanbevelingen en de moduletekst ten behoeve van de leesbaarheid.
- Naar aanleiding van de commentaren zijn de aanbevelingen van uitgangsvraag 3b aangepast. De twee aanbevelingen over het voorschrijven van medicatie zijn verwijderd omdat de meeste verpleegkundigen geen medicatie mogen voorschrijven en deze aanbevelingen daardoor voor verwarring zorgden. Richtlijnen voor medicatie bij incontinentie passen beter bij het NHG of bij de medische specialismen zoals urologie.
- De aanbeveling over bijwerkingen vond de werkgroep wel zodanig belangrijk dat deze niet verwijderd kon worden. Wel is de aanbeveling iets aangepast omdat de voorschrijver al de cliënt en/of mantelzorgers geïnformeerd moet hebben over bijwerking. De werkgroep denkt wel dat de wijkverpleging alert kan zijn op bijwerkingen die de kwaliteit van leven van de client kunnen beïnvloeden.
-

Evidence tabellen

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Abreu-Mendes-2021 EUROPEAN UROLOGY FOCUS Worldwide SLR	To review the key studies involving pharmacological and neuromodulation treatment of LUTS published from 2018 onward	*Type of incontinence* Lower urinary tract symptom; overactive bladder; detrusor overactivity *Intervention* - Mirabegron vs placebo - Vibegron vs placebo - Mirabegron plus solifenacin vs monotherapy mirabegron or solifenacin) - Tamsulosin + mirabegron vs. tamsulosin + placebo - Tadalafil plus - Mirabegron vs. tadalafil - Sacral neuromodulation - vs onabotulinum toxinA	*Inclusion criteria* • RCTs; prospective/retrospective cohort series • English language • Conference/ international meeting abstracts *Exclusion criteria* • Preclinical trials • Studies including neurogenic OAB patients. Moreover, articles corroborating previously established data about these therapies, even if clinically relevant, were also excluded, given the absence of relevance for the objective of this paper, to update	*Search strategy* Pubmed and EMBASE; Articles published between January 2018-January 2020; Search strategy was reported in article (very broad search). How conference- and international meeting abstracts were collected, was not described PRISMA flow chart presented in the article. *Numbers of included articles* **SLR:** 46 articles publications were included. Table with summary of manuscripts and abstracts shows 20 studies which are relevant for the V&VN guideline *Study endpoints* Not predefined

Results	Conclusion and Remarks
Anticholinergic drugs - Exposure to AC drugs is associated with an increased risk of dementia - Only male patients, >65 yr, with high AC burden and long AC treatment duration were at a higher risk of developing dementia - The use of AC in OAB patients was associated with an increased risk of new-onset dementia compared with mirabegron users *Mirabegron vs. placebo*	*Conclusion* **Mirabegron** was shown to be effective and safe across all age groups and both sexes. **Vibegron** was extensively studied for the first time, enriching the beta-3 class. Exposure to mirabegron was not associated with cognitive impairment, in contrast to treatment with antimuscarinic drugs. Different combination therapies were evaluated to increase the efficacy of available drugs in monotherapy. *Remarks* - This SLR included all studies with a variety of study populations; treatment options and study endpoints.

Symptom scores:
 	
- Improvements on incontinence: Significant improvement compared to placebo
- Voiding episodes: Significant improvement compared to placebo; Trend toward an overall reduction in the number of voids per day was found
- Maximum flow rate: changes were clinically irrelevant
- Postvoid residual: changes were clinically irrelevant
 	
Mirabegron (observational)
 	
Symptom scores:
 	
- Bothersome symptoms: Improved significantly before using the medication
- Percentage of dry patients increased by about 10% at the end of the study, with a concomitant decrease in pad use
 	
Quality of life:
 	
- Improved significantly before using the medication
 	
Mirabegron plus solifenacin vs monotherapy mirabegron or solifenacin
 	
Combination therapy for OAB demonstrates favorable longterm safety and efficacy profile.
 	
Vibegron vs placebo
 	
Symptom scores:
 	
- Number of micturition per 24 hr: Significant improvement compared to placebo
- Number of urgency during the day: >50% of the patients exposed to vibegron becoming dry.
- Number of incontinence episodes during the day: >40% of the patients exposed to vibegron, reported normalization of nocturia.
- Number of voids per day: significantly improved compared with placebo
 	
Combination therapy
 	
- The combination of mirabegron+ solifenacin was compared against each drug in monotherapy. The improvement in frequency, urgency, and UUI favored the combination arm.
- The vibegron alone or in combination with tolterodine in improving daily micturition frequency and reducing incontinence episodes in OAB wet patients.
	- No meta-analysis was performed
	- Definition of type of UI was not reported
	- Study endpoints were not predefined. Also, the endpoints were not defined.
	- Results about safety can be found in the article.
	- No limitation section was written in the article.
	
	Results of AMSTAR
	- In-exclusion criteria and PICO (no)
	- Statement of pre-defined protocol (no)
	- Comprehensive literature study (partial yes)
	- Study selection in duplicate (no)
	- Data extraction in duplicate (no)
	- List of excluded articles (no)
	- Included studies described in adequate detail (no)
	- Risk of bias assessment (no)
	- Meta-analyse: nvt
	  - Appropriate methods for statical combination (nvt)
	  - Impact of RoB (nvt)
	  - Heterogeneity (nvt)
	  - Publication bias (nvt)
	- Conflict of interest (no)

LUTS: Lower urinary tract symptom; OAB: Overactive bladder; RCT: Randomised controlled trial; SLR: systematic literature review

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Albarqouni-2021 ANNALS OF FAMILY MEDICINE Worldwide SLR+ MA	To evaluate the effects of self-management interventions on Lower urinary tract symptoms in males	*Type of incontinence* Urinary tract symptoms whether storage symptoms, voiding symptoms, or both *intervention* - Self-management interventions vs usual care* - Self-management interventions vs drug therapy - Combination of self-management + drug therapy vs. drug therapy alone	*Inclusion criteria* • RCTs • Male (when both sexes included, only data from the male were included) • Scope: Worldwide • No language or date restrictions *Exclusion criteria* • Involved men who had lower urinary tract symptoms attributed to infections (e.g., urinary tract infection or prostatitis) • Male who had prostate cancer or had undergone prostate surgery • Male who had undergone prostate surgery, • Male with concomitant neurologic conditions (e.g., stroke or Parkinson disease).	*Search strategy* PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials; No restrictions on date were used. Search was performed on 10 July 2019. Full search strategy was reported in the supplement; The database searches were supplemented with a backward and forward citation search of included studies using the Scopus database PRISMA flow chart presented in the article *Numbers of included articles* **SLR**: 14 articles reporting on 8 RCTs **Meta analyses**: 12 articles reporting on 6 RCTs ➔ Four studies were relevant for the V&VN guideline. *Study endpoints* <u>Self-management vs. drug therapy</u> - Validated symptom scores/severity (the International Prostate Symptom Score (IPSS) and the American Urological Association Symptom Index (AUA-SI: (4 studies; 302 participants). - Symptom frequency at 6-12 weeks: o Nucturia episodes (3 studies; 311 participants) o 24-hour voiding frequency (2 studies; 263 participants) - Serious adverse events (1 study; 139 participants) - Patients' perception of bothersome side effects (n=2; 252 participants) <u>Combination of self-management + drug therapy vs. drug therapy alone</u> - Symptom severity at 6-12 weeks) (not further specified; 1 study; 133 participants) - Symptom frequency:

				○ Nucturia episodes at 6-12 weeks (2 studies; 182 participants) ○ 24-hour voiding frequency (1 study; 133 participants)

Results	Conclusion and Remarks
Self-management vs. drug therapy: results based on meta-analyses Symptom scores: **No evidence** of a difference in symptom severity [Mean difference: 0.00; 95% CI: -1.95-1.96] Symptom frequency: - Nucturia episodes: **Significant difference** favouring self-management [mean difference: --0.42; 95% CI: -0.67—0.17] - 24-hour voiding frequency: **No evidence** of a difference in 24-hour voiding frequency [Mean difference: –0.96; 95% CI, –2.04-0.12] - Serious adverse events→ No MA. More SAEs were found in drug therapy - Patients' perception of bothersome side effects: Participants in the **drug therapy group reported side effects 26% more frequently** than peers in the self-management group [risk difference: -0.95; 95% CI-4.11- --0.49 *Combination of self-management and drug therapy vs. drug therapy alone* Symptom scores: **combination significantly reduced symptom** severity on the IPSS compared with drug therapy alone at 6 weeks (mean difference: –2.30; 95% CI, –4.11 to –0.49) Symptom frequency: - Nucturia episodes: male in the combined intervention group reported fewer episodes of nocturia (mean difference = –0.45; 95% CI –0.77 to –0.14) - 24-hour voiding frequency: male in the combined intervention group reported less voiding in 24 hours (mean difference: -2.10; 95% CI: -2.95- -- 1.25)	*Conclusion* The study found moderate-quality evidence (suggesting reasonable certainty in estimates) for the effectiveness of self-management for treating lower urinary tract symptoms in men. We therefore recommend the use of self-management interventions for this patient population *Remarks* - Not all included studies are relevant for the V&VN. In the results section of this table, only the relevant data are shown. - RCTs included in the MA were very small. *Results of AMSTAR* - In-exclusion criteria and PICO (yes) - Statement of pre-defined protocol (yes) - Comprehensive literature study (yes) - Study selection in duplicate (yes) - Data extraction in duplicate (yes) - List of excluded articles (yes) - Included studies described in adequate detail (yes) - Risk of bias assessment (yes) - Meta-analyse: ○ Appropriate methods for statical combination (yes) ○ Impact of RoB (no) ○ Heterogeneity (yes) ○ Publication bias (no) - Conflict of interest (no)

* The data about self-management vs. usual care are not reported in this table.

CI: confidence interval; IPSS: the International Prostate Symptom Score; RCT: randomized controlled trail; RoB: risk of bias; SLR: systematic literature review;

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Ebell-2014 THE JOURNAL OF UROLOGY Worldwide SLR + MA	To review the efficacy and safety of desmopressin for nucturia in adults, focusing on benefits and harms	*Type of incontinence* Nucturia (at least 2 nighty voids per day) *intervention* Desmopressin vs placebo	*Inclusion criteria* • RCTs • Adults *Exclusion criteria* • Children • Specialized populations (e.g. cancer or cushing disease). Not further specified	*Search strategy* Pubmed; Articles published till April 2013 (updated in November 2013 but no additional articles were found); Full strategy was reported in the article; No PRISMA flow-chart was presented in the article/ supplement. *Numbers of included articles* **SLR:** 10 RCTs **MA:** 9 RCTs *Study endpoints* **Efficacy results** - Number of nocturnal voids (8 studies; 2007 participants) - Time to first void of first sleep duration (7 studies; 1419 participants) - Overall clinical response assed by the patient (9 studies; 1953 participants) **Safety results** - Hyponatremia (1 study: 115 participants) - Headache (6 studies; 662 participants) - Severe adverse events (7 studies; 1838 participants) - Overall clinical response assed by the patient (9 studies; 1953 participants)

Results	Conclusion and Remarks
Desmopressin (dose <100 mg) vs. placebo based on meta-analysis	*Conclusion* Desmopressin appears to be safe, effective treatment of nocturia in generally healthy adults. The initial dose should be between 50 and 100 mcg. Higher doses do not appear to provide a greater benefit and should only be used with caution. A lower initial dose of 25 to 50 mcg is appropriate in elderly patients. All

Number of nocturnal voids: Significant reduction of nocturnal voids per night [weighted mean difference: -0.30; 95% CI: -0.43 - -0.16] Time to first void of first sleep duration: Treated patients received significant more sleep minutes than controls [weighted mean difference: 42,18; 95% CI: 19.94 – 64.42] *desmopressin (dose ≥100 mg) vs. placebo* based on meta-analysis Number of nocturnal voids: Significant reduction of nocturnal voids per night [weighted mean difference: -0.50; 95% CI: -0.65 - -0.35] Time to first void of first sleep duration: Treated patients received significant more sleep minutes than controls [weighted mean difference: 57.65; 95% CI: 39.21 – 76.10] *Safety results and Overall clinical response: see article*	patients should be monitored for hyponatremia and the drug should be used with caution in patients with chronic lung disease due to the rare development of respiratory failure. *Remarks* - In/exclusion criteria were not reported in detail - Included also studies with a study population with a mean/median age <60 - Very broad study search - In only one database was searched - The study was limited by heterogeneity due to different doses, study designs, inclusion criteria and study populations by age and gender - Another limitation was inconsistent reporting of treatment harms such as hyponatremia. *Results of AMSTAR* - In-exclusion criteria and PICO (yes) - Statement of pre-defined protocol (no) - Comprehensive literature study (no) - Study selection in duplicate (yes) - Data extraction in duplicate (yes) - List of excluded articles (no) - Included studies described in adequate detail (no) - Risk of bias assessment (yes) - Meta-analyse: o Appropriate methods for statical combination (yes) o Impact of RoB (no) o Heterogeneity (yes) o Publication bias (no) - Conflict of interest (no)

CI: confidence interval; MA: meta-analysis; Mg: milligram; RCT: randomised controlled trail; SLR: systematic literature review

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Hsu-2019 Worldwide International Urogynecology Journal SLR	To compare the effectiveness of drugs approved by the FDA to treat OAB symptoms	*Type of incontinence* OAB, UUI and mixed incontinence *intervention* - Darifenacin - Fesoterodine - Oxybutynin - Solifenacin - Tolterodine - Trospium - Mirabegron	*Inclusion criteria* • Adults with symptoms of OAB, including UUI and mixed incontinence, were included • RCTs • Doses approved by the FDA • publications in English *Exclusion criteria* • Studies of patients with only stress incontinence or neurogenic detrusor overactivity were excluded • Animal studies	*Search strategy* MEDLINE, MEDLINE In-Process, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews; Articles published between 2011 to September 2018 (not further specified); Full search strategy was reported in the supplement; PRISMA flow chart presented in the article *Numbers of included articles* **SLR:** 41 articles based on 20 RCTs→ the article only reports on the 15 RCTs with good (n=5) or fair (n=10) quality *Study endpoints* **Efficacy results** (n=NR; participants NR) - Number of incontinence episodes - Number of urgency (grade 3 or 4) episodes - Micturition frequency - Proportion of patients reporting no incontinence over 3 days at end of study - Patient-reported symptom assessment: o the Patient Perception of Bladder Condition (PPBC), o Overactive Bladder Questionnaire(OAB-q) Symptom Bother score, o The Overactive Bladder Symptom Score (OABSS) **Safety outcomes** (n=NR; participants NR) - Withdrawals due to adverse events - Number of SAEs - Blurred vision - Constipation - Dizziness - Dry mouth

				- QT prolongation - Arrhythmia - Other cardiac outcomes

Results	Conclusion and Remarks

Mirabegron + solifenacin vs. solifenacin
 	
Incontinence episodes in 24 h (4 RCTs; 6430 participants): The combination of mirabegron 50 mg with solifenacin 5 mg showed significant improvement compared with solifenacin 5mg. However, patients still experienced more than one incontinence. Moreover, the absolute difference between combination therapy and monotherapy was less than one episode of incontinence [mean difference -0.18; 95% CI: -0.31- -0.05]
 	
Proportion of patients reporting no incontinence over 3 days at end of study (n=3; participants NR): The combination of mirabegron 50 mg with solifenacin 5 mg showed significant improvement compared with solifenacin 5mg [risk ratio: 1.23; 95% CI: 1.13-1.34]
 	
Urgency episodes in 24 h (4 RCTs; 6430 participants): The combination of mirabegron 50 mg with solifenacin 5 mg showed significant improvement compared with solifenacin 5mg. However, patients still experienced about three urgency episodes per day. Moreover, the absolute difference between combination therapy and monotherapy was less than one episode urgency [Mean difference: -0.58; 95% CI: 0.89 - -0.28)
 	
Micturition frequency in 24 h (4 RCTs; 6430 participants): The combination of mirabegron 50 mg with solifenacin 5 mg showed significant improvement compared with solifenacin 5mg. Moreover, the absolute difference between combination therapy and monotherapy was less than one episode of micturitions per day [mean difference: -0.41; 95% CI: -0.54 - -0.27]
 	
Efficacy results: Mirabegron plus solifenacin vs. mirabegron
 	
Incontinence episodes in 24 h (3 RCTs; 3677 participants): mirabegron 50 mg plus solifenacin 5 mg per day significantly improved all other efficacy outcomes more than mirabegron 50 mg per day at 12 weeks [mean difference -0.34; 95% CI: -0.52- -0.16]
	Conclusion
	
	New evidence confirms small, but clinically uncertain, differences among monotherapies and also between combination and monotherapy, regardless of statistical significance. While drugs mainly differed in incidence of dry mouth or constipation, none provided improved efficacy without increased harms.
	
	Remarks
	- This SLR is an update of an SLR performed in 2012. Only data from the new studies found in the update are presented. Only results from the meta-analysis are shown.
	- Mean age of all studies combined was 57.4 years
	- The number of included RCTs and participants was not always reported per study outcome.
	- Limitations mentioned by the author: Potentially include the lack of a network meta-analysis and quality of life measures reported in some studies. These were not undertaken because of the scope, timeline, and resource limitations defined by the DERP patients who funded the initial work. Also, adverse events reporting was inconsistent among trials. Some trials reported “common anticholinergic effects,” some only reported adverse effects that affected > 2% of patients, and others reported the most common complaints reported by patients. As a result, not all harm outcomes of interest were reported by all trials, particularly blurred vision, cardiac arrhythmias, dizziness, and fall/syncope. In addition, the value and contribution of quality-of-life assessment in overactive bladder are unclear
	
	Results of AMSTAR
	- In-exclusion criteria and PICO (yes)
	- Statement of pre-defined protocol (yes)
	- Comprehensive literature study (yes)
	- Study selection in duplicate (yes)
	- Data extraction in duplicate (no)
	- List of excluded articles (no)
	- Included studies described in adequate detail (yes)
	- Risk of bias assessment (yes)
	- Meta-analyse:
	  o Appropriate methods for statical combination (yes)
	  o Impact of RoB (yes)
	  o Heterogeneity (yes)
	  o Publication bias (yes)
	- Conflict of interest (yes)

Proportion of patients reporting no incontinence over 3 days at end of study (n=2); participants NR): Mirabegron (50mg) + solifenacin (5 mg) did not significantly improved compared to mirabegron. [risk ratio: 1.18; 95% CI: 0.98 – 1.41] Urgency episodes in 24 h (3 RCTs; 3677 participants): Mirabegron 50 mg plus solifenacin 5 mg per day significantly improved all other efficacy outcomes more than mirabegron 50 mg per day at 12 weeks [Mean difference: -0.77; 95% CI: -1.02 - -0.52) Micturition frequency in 24 h (3 RCTs; 3677 participants): Mirabegron 50 mg plus solifenacin 5 mg per day significantly improved all other efficacy outcomes more than mirabegron 50 mg per day at 12 weeks [mean difference: -0.56; 95% CI: -0.75 - -0.37] *Efficacy results: Mirabegron vs. solifenacin* Incontinence episodes in 24 h (4 RCTs; participants NR): solifenacin (5 mg) significantly reduced incontinence episodes more than mirabegron (50 mg) [mean difference +0.20; 95% CI: 0.02-0.38] Proportion of patients reporting no incontinence over 3 days at end of study (n=3; participants NR): There was no difference in the number of patients reporting no incontinence between mirabegron vs. solifenacin [risk ratio: 1.01; 95% CI: 0.93 – 1.09] Urgency episodes in 24 h (4 RCTs; participants NR): a significant difference was not found in reduction of urgency episodes from baseline [Mean difference: +0.19; 95% CI: -1.02 - 0.52) Micturition frequency in 24 h (3 RCTs; participants NR): solifenacin reduced micturition frequency significantly more than mirabegron [mean difference: +0.18; 95% CI: 0.01 - 0.35] ***Efficacy results:*** **Mirabegron vs. tolterodine ER** Incontinence episodes in 24 h (n=5; participants NR): Meta-analyses showed no difference in any efficacy outcome between drugs [mean difference -0.12; 95% CI: -0.26-0.03]	

Proportion of patients reporting no incontinence over 3 days at end of study(n=4; participants NR): Meta-analyses showed no difference in any efficacy outcome between drugs. Forty-seven percent of patients in both treatment groups reported no incontinence over 3 days at the end of treatment [risk ratio: 1.01; 95% CI: 0.92 – 1.11] Urgency episodes in 24 h (n=5; participants NR): Meta-analyses showed no difference in any efficacy outcome between drugs [Mean difference: -0.01; 95% CI: -0.19 - 0.17) Micturition frequency in 24 h (6 RCTs; 4904 participants): Meta-analyses showed no difference in any efficacy outcome between drugs [mean difference: -0.18; 95% CI: -0.43 - 0.06] *Efficacy results:* Fesoterodine vs. tolterodine Incontinence episodes in 24 h (3 RCTs; 4148 participants): Although fesoterodine led to statistically fewer incontinence and urgency episodes per day, the absolute differences were small at less than one-half episode per day for each efficacy outcome [mean difference -0.18; 95% CI: -0.29--0.07] Proportion of patients reporting no incontinence over 3 days at end of study (n=2; participants NR): Patients reporting no incontinence at end of treatment also favoured fesoterodine (64% vs. 58%). [risk ratio: 1.10; 95% CI: 1.04 – 1.16] Urgency episodes in 24 h (3 RCTs; 4148 participants): Although fesoterodine led to statistically fewer incontinence and urgency episodes per day, the absolute differences were small at less than one-half episode per day for each efficacy outcome [Mean difference: -0.40; 95% CI: -0.69 - -0.12) Micturition frequency in 24 h (3 RCTs; 4148 participants): Although fesoterodine led to statistically fewer incontinence and urgency episodes per day, the absolute differences were small at less than one-half episode per day for each efficacy outcome [mean difference: -0.22; 95% CI: -0.43 - -0.01] ***Efficacy results:* Solifenacin vs. tolterodine**	

Incontinence episodes in 24 h (n=4; participants NR): Meta-analysis of four studies indicated that solifenacin 5 mg significantly improved incontinence and urgency episodes per day [mean difference -0.36; 95% CI: -0.58- -0.13] Urgency episodes in 24 h (n=4; participants NR): Meta-analysis of four studies indicated that solifenacin 5 mg significantly improved incontinence and urgency episodes per day- [Mean difference: -0.40; 95% CI: -0.69 - -0.12) Micturition frequency in 24 h (n=4; participants NR): The difference in micturitions did not reach statistical significance [mean difference: -0.20; 95% CI: -0.45 - 0.05] ***Efficacy results:*** **Solifenacin vs. oxybutynin (1 RCT; 132 participants)** Urgency episodes in 24 h: no difference in urgency episodes per day or number of micturitions [Mean difference: +1.05; 95% CI: -0.55 - 2.65) Micturition frequency in 24 h: no difference in urgency episodes per day or number of micturitions mean difference: +0.80; 95% CI: -0.43 – 2.03] *Efficacy results: Tolterodine vs.oxybutynin* Incontinence episodes in 24 h (n=8; participants NR): [mean difference +0.01; 95% CI: -0.25--0.28] Proportion of patients reporting no incontinence over 3 days at end of study (n=1; participants NR): [risk ratio: 0.73; 95% CI: 0.55– 0.97] Micturition frequency in 24 h (n=8; participants NR): [mean difference: -0.16; 95% CI: -0.49 - 0.18] *Safety results:* Although mirabegron is not an anticholinergic drug, it exhibits some adverse effects similar to anticholinergics. Pooled analyses found no difference between mirabegron 50 mg and solifenacin 5 mg or tolterodine ER 4 mg related to blurred vision, cardiac arrhythmia, constipation, or dizziness. While incidence of dry mouth was significantly lower in patients who received mirabegron, this was not reflected in the rate of withdrawal due to adverse events. At 52 weeks, the difference in incidence of dry mouth between mirabegron and solifenacin was no longer significant, though a significant difference remained between	

mirabegron and tolterodine. When choosing between mirabegron and solifenacin, clinicians should consider their comparable safety profile but solifenacin's greater effectiveness on incontinence and micturition frequency	

CI: confidence interval; FDA: Food and Drug Administration; MG: milligram; NR: not reported; OAB: Overactive bladder; RCT: Randomized controlled trials; SAE: serious adverse events; UUI: Urge urinary incontinence

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Lozano-Ortega-2019 Worldwide UROLOGY SLR + MA	To compare the efficacy and safety of mirabegron and onabotulinumtoxinA in the management of treatment-experienced patients with overactive bladder	Type of incontinence Overactive bladder (OAB) defined as idiopathic overactive bladder, or idiopathic urge urinary incontinence, or non-neurogenic urge urinary incontinence, or refractory detrusor over activity, with/without urinary incontinence) Intervention (daily doses, except onabotulinumtoxinA): - Mirabegron (25 and 50 mg)	*Inclusion criteria* • adults (≥18 years) with OAB who have received at least one prior OAB pharmacotherapy (to be eligible for inclusion, at least 80% of the patient population described in the study was required to be treatment-experienced, or have endpoints reported for the subgroup of treatment-experienced patients) • An a priori decision was made to include studies that compared two or more antimuscarinics or compared an antimuscarinic to a placebo, as they had the potential of contributing intermediate information to the network of evidence, for the comparison of mirabegron versus onabotulinumtoxinA, even though antimuscarinics themselves were not comparators of interest	*Search strategy* Medline and Medline in-progress (OVID SP), EMBASE (OVID SP) (which includes the Cochrane Central Register of Controlled Trials [CENTRAL]), and PubMed; Articles published between 01-01-2005 to 21-08-2018; Full search strategy was reported in the supplement; PRISMA flow chart presented in the article *Numbers of included articles* **SLR:** 21 articles representing 19 RCTs **Network-MA:** 15 articles representing 13 studies

		- OnabotulinumtoxinA (100 U) Comparators: Antimuscarinic therapies: - Darifenacin (7.5, 15 mg) - Fesoterodine (4, 8 mg) - Oxybutynin (transdermal patch: 3.9 mg; gel: 100 mg; syrup: 5 mg; tablet: 5, 10, 15 mg) - Solifenacin (5, 10 mg) - Tolterodine (1, 2, 4 mg) - Trospium chloride (60 mg) - Placebo	• Only treatments approved for use in the US and placebo were eligible *Exclusion criteria* • Studies including patients with OAB and urinary incontinence with a known cause (eg surgery, pregnancy, benign prostatic hyperplasia, bladder outlet obstruction, spinal cord injury) or with any of the following conditions: neurogenic OAB, stress urinary incontinence, bladder oversensitivity, or bladder hypersensitivity were excluded	*Study endpoints* **Efficacy results** (n=13): - Incontinence episodes per 24 h (12 studies; 6283 participants), - Total micturition's per 24 h (12 studies; 6178 participants) - Nucturia episodes per 24 h (4 studies;3348 participants) - Volume voided per micturition (3 studies; 709 participants)→ No MA - Urgency episodes per 24 h (5 studies; 3067 participants). **Safety results** (n=12): - Patients with treatment-emergent adverse events (8 studies; 3982 participants) - Patients with adverse-event related treatment discontinuation (9 studies; 4027 participants - Overall treatment discontinuation (9 studies; 4027 participants) - Patients with urinary retention (6 studies; 3588 participants) - Patients with urinary tract infection (8 studies; 3853 participants) - Patients with voiding difficulty due to dysuria (3 studies; 1446 participants) - Patients with severe treatment-emergent adverse events (5 studies; 3190 participants) - High blood pressure (2 studies; 2044 participants) - SBP (1 study; 1870 participants) - DBP (1 study; 1870 participants)

Results	Conclusion and Remarks
Efficacy results: mirabegron 50 mg vs. onabotulinumtoxinA. based on network meta-analysis <u>Number of micturitions per 24 h:</u> A greater reduction in the total number of micturitions for onabotulinumtoxinA relative to mirabegron 50 mg (not statistically significant) [mean difference: -0.43; 95% CrI: -1.22- 0.37] <u>Incontinence episodes per 24 h:</u> onabotulinumtoxinA was weakly associated with a reduction in the total number of incontinence episodes relative to mirabegron 50 mg (Mean difference: -0.46; CrI: -1.46 - 0.53)	*Conclusion* Overall, compared to mirabegron, there was some evidence that onabotulinumtoxinA was associated with improved outcomes, including reductions in the number of micturitions in a 24-hour period, and the number of incontinence episodes. However, mirabegron was associated with a lower risk of urinary tract infections compared with onabotulinumtoxinA *Remarks* - Possibly some overlap with Lazano-Ortega-2019 - Limitations mentioned by the author: This NMA incorporated evidence from the subset of eligible treatment-experienced patients in mirabegron studies where the overall population did not meet the inclusion criteria of the systematic search. While these additional data provided important evidence in the comparisons of interest, conducting posthoc analyses restricts the analysis to only a subset of the overall study population, limiting power and excluding a portion of the mirabegron evidence base. Baseline characteristics were compared between the full study population and the subset of treatment-experienced patients (data available upon request). Overall, baseline characteristics aligned with those reported in the original studies, suggesting that limiting the population to

Nocturia episodes per 24 h: Mirabegron 50 mg was estimated to be similarly efficacious to onabotulinumtoxinA at reducing nocturia episodes (mean difference: 0.03; CrI: -0.30 - 0.38) *Efficacy results: mirabegron 50 mg vs. pooled-placebo. based on network meta-analysis* Number of micturitions per 24 h: A greater reduction in the total number of micturitions for onabotulinumtoxinA relative to mirabegron 50 mg (not statistically significant) [mean difference: -0.43; 95% CrI: -1.22- 0.37] Incontinence episodes per 24 h: onabotulinumtoxinA was weakly associated with a reduction in the total number of incontinence episodes relative to mirabegron 50 mg (Mean difference: -0.46; CrI: -1.46 - 0.53) Nocturia episodes per 24 h: Mirabegron 50 mg was estimated to be similarly efficacious to onabotulinumtoxinA at reducing nocturia episodes (mean difference: 0.03; CrI: -0.30 - 0.38) ***Safety results:*** *In the RE model, onabotulinumtoxinA was associated with greater odds of UTI relative to mirabegron 50 mg (OR = 2.97, CrI: 0.87, 10.21) (Fig. 3),*	treatment-experienced patients did not induce other major differences to population makeup. While all NMAs are limited by the heterogeneity of the patient characteristics, the post-hoc analysis was undertaken to create a more homogeneous patient population than previous NMAs conducted in patients with OAB. Potential residual heterogeneity includes the fact that while patients in the mirabegron and antimuscarinics trials may have had prior experience with antimuscarinics, some may not have failed treatment; in contrast, those in onabotulinumtoxinA studies most likely had already failed several other treatment. - There were some inconsistencies within the article/supplementary data regarding to the number of studies included per study endpoint *Results of AMSTAR* - In-exclusion criteria and PICO (yes) - Statement of pre-defined protocol (no) - Comprehensive literature study (partial yes) - Study selection in duplicate (yes) - Data extraction in duplicate (no) - List of excluded articles (no) - Included studies described in adequate detail (no) - Risk of bias assessment (yes) - Meta-analyse: o Appropriate methods for statical combination (yes) o Impact of RoB (no) o Heterogeneity (yes) o Publication bias (no) - Conflict of interest (No)

CI: confidence interval; CrI: credible interval; DBP: Diastole blood pressure; Mg: milligram; NMA: Network-meta-analysis; OAB: Overactive bladder; RCT: randomized controlled trial; SBP: Systole blood pressure; US: United States

Author, year, country, journal, type of study	Study objective	Type of incontinence; intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Lozano-Ortega-2020 Drugs & Aging	To indirectly compare the safety and efficacy profile of mirabegron relative to antimuscarinics in older adults (aged ≥ 65 year) with overactive bladder	*Type of incontinence* - Overactive bladder (AOB) - Nocturia - Urge incontinence	*Inclusion criteria* • RCTs • OAB treatments (solifenacin, tolterodine, darifenacin, fesoterodine, oxybutynin, trospium, mirabegron) and doses that are approved in the USA • Scope: Worldwide	*Search strategy* MEDLINE, EMBASE and Pubmed; Articles published between 01-01-2000 to 21-08-2018; Full search strategy was reported in the supplement;

Worldwide
 	
SLR + MA
		Interventions
		
		- Mirabegron
		- Antimuscarinics:
		  ○ Darifenacin
		  ○ Fesoterodine
		  ○ Mirabegron
		  ○ Oxybutynin
		  ○ Solifenacin
		  ○ Tolterodine chloride
		- Placebo
			• Only studies where at least 80% of participants were aged 65 years or older, or those that reported results separately for this subgroup of individuals, were considered.
			• Conference abstracts
			• Additional inclusion criteria for meta-analyse: Endpoints reported at 12 weeks (± 1 week)
			• English language
			
			Exclusion criteria
			
			• Participants had a known aetiology of their bladder dysfunction such as neurogenic detrusor overactivity, stress urinary incontinence, bladder oversensitivity, bladder hypersensitivity, nocturia only, or interstitial cystitis only.
			• Phase I studies and cross-over studies where results were not reported before cross-over occurred were also excluded.
			• Studies were not restricted by a patient's prior anticholinergic use; however, a washout period of several weeks was often implemented, and concomitant use during the trials was either restricted or not reported.
				PRISMA flow chart presented in the article
				
				Numbers of included articles
				
				SLR: 20 studies reporting on 21 RCTs
				
				Network-meta analyses: 14 RCTs
				
				Study endpoints
				
				Efficacy results (n=13):
				
				- Incontinence episodes per 24 h (7 studies; 3317 participants),
				- Urgency incontinence episodes per 24 h (8 studies; 4878 participants)
				- Micturitions per 24 h (13 studies; 8313 participants),
				- Volume voided per micturition (7 studies; 4610 participants),
				- Urgency episodes per 24 h (9 studies; 5847 participants)).
				
				Safety results (n=12):
				
				- Dry mouth and constipation (11 studies; 7170 participants),
				- Overall TEAEs (7 studies; 6374 participants),
				- AE-related treatment discontinuations (8 studies; 6937 participants)

Results	Conclusion and Remarks
Efficacy results: AOB medication vs. placebo based on network meta-analysis <u>Number of incontinence episodes per 24 h:</u> Compared to antimuscarinics, mirabegron had **the strongest association with the reduction** relative to placebo (mean: − 0.65 episodes [95% CrI− 1.23 to− 0.10]. While solifenacin was associated with a slightly higher reduction in incontinence episodes, the inclusion of the null value in the 95% CrI indicated the presence of a weaker evidence base (− 0.67 episodes [− 1.39 to 0.01]). <u>Urgency incontinence episodes per 24 h</u>: fesoterodine had the strongest evidence for its	*Conclusion* The evidence provided by this study indicates that among older adults, the **efficacy** of mirabegron is **similar** to that of antimuscarinics. Furthermore, the safety profile of mirabegron relative to that of antimuscarinics remained favourable in this subpopulation of older adults with OAB. This study provides evidence that the **safety** of antimuscarinics is **less favourable** relative to mirabegron in this population. *Remarks* - Limitations mentioned by the author: Most of the studies included in the NMA randomized adults of all ages, whereas the results considered here were based on post-hoc analyses on sub-groups who were aged 65 years or older. Therefore, it is unknown whether such results were differentially reported in studies for which positive results were observed in the subgroups, and there is potential for bias in the estimates owing to differences in treatment-effect modifiers that may have been present among those of an older age, given that this subgroup was not specifically a product of

association with a reduction in urgency incontinence episodes (− 0.43 episodes [− 0.81 to − 0.05]), while mirabegron and solifenacin were each associated with a larger reduction but weaker evidence (mirabegron: − 0.57 episodes [− 1.31 to 0.17]; solifenacin: − 0.61 episodes [− 1.74 to 0.52]). Micturitions per 24 h: Strong associations among both mirabegron and antimuscarinics (with the exception of oxybutynin and tolterodine) Urgency episodes per 24 h: Strong associations among both mirabegron and antimuscarinics (with the exception of oxybutynin and tolterodine) Volume voided per micturition: Strong associations among both mirabegron and antimuscarinics (with the exception of oxybutynin and tolterodine) *Safety results:* both dry mouth and constipation, mirabegron was not associated with an increased odds of these events relative to placebo (OR, 95% CrI 0.76 [0.26–2.37] and 1.08 [0.39–3.02], respectively). Conversely, antimuscarinics were strongly associated with an increased odds of dry mouth and constipation. Neither mirabegron nor antimuscarinics were strongly associated with an increased odds of overall TEAEs, with the exception of fesoterodine, in the base case. In the sensitivity analysis, antimuscarinics were strongly associated with an increased odds for TEAEs relative to placebo (1.46 [1.05–2.05]), while mirabegron was weakly associated with a higher odds relative to placebo (OR, 95% CrI 1.32 [0.78–2.27]).	randomization. This could not be thoroughly investigated because baseline characteristics for the 65 years of age or older subgroup were not consistently presented across all included studies. - Possibly some overlap with Lazano-Ortega-2019 *Results of AMSTAR* - In-exclusion criteria and PICO (yes) - Statement of pre-defined protocol (no) - Comprehensive literature study (yes) - Study selection in duplicate (yes) - Data extraction in duplicate (no) - List of excluded articles (no) - Included studies described in adequate detail (yes) - Risk of bias assessment (yes) - Meta-analyse: o Appropriate methods for statical combination (yes) o Impact of RoB (no) o Heterogeneity (yes) o Publication bias (no) - Conflict of interest (yes, described in detail)

AE: adverse events; AOB: Over active bladder; CrI: the posterior credible interval; h: hour; NMA: network meta-analysis; RCT: randomized controlled trail; RoB: risk of bias; TEAS: treatment-emergent adverse events; USA: United States of America;

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Riemsma-2017 BMC medicine	To assess cure rates from treating UI or FI and the number of people who may remain dependent on containment strategies.	*Type of incontinence* UI: Defined as involuntary loss of urine according to International Continence Society/International Urogynecological	*Inclusion criteria* • Any design • Adult patients (≥18 years) with UI or FI • Reporting cure or success rates • Sample size: ≥ 50 patients • Evaluating any intervention in line with the 5th International Consultation on	*Search strategy* Medline, Embase, PsycINFO, the Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, and PEDro; Articles published between January 2005 till June 2015; Full strategy was not reported in the article;

Worldwide SLR		Association terminology (SUI; UUI; MUI) *Intervention* any intervention in line with the 5th International Consultation on Incontinence (ICI) treatment algorithms (which includes primary, secondary and additional lines of therapy)	incontinence treatment algorithms (which includes primary, secondary and additional lines of therapy) • A follow-up time ≥ 3 months *Exclusion criteria* • NR	PRISMA flow-chart was presented in the article; Included also conference abstracts. *Numbers of included articles* **SLR:** 127 articles of 98 studies (not all studies are relevant for our guideline) **MA:** NA *Study endpoints* **Efficacy results** - Cure rates (N of studies not reported) - Improvements/success rates (N of studies not reported): the percentage of patients with no limitations to activities of daily living, quality of life, or social interaction

Results	Conclusion and Remarks
SUI No cure rates were reported for treatment with medications **UUI** Darifenacin (1 study): 38% after 3 months; 41% after 6 months; 42% after 12 months; 43.8% after 24 months (all women) Fesoterodine (5 studies): 49.2%; 57.8%; 62%; 63%; 64% after 3 months (all women) Oxybutynin (2 studies): 20%; 25.2% after 3 months (all women) Solifenacin (5 studies): 56.2%; 58%; 59%; 59.6% after 3 months; 11% after 6 months; 58%; 60% after 12 months (all women). Two studies reported data for 5 and 10 mg of solifenacin: 56.2% vs. 59.6% after 3 months; 58% vs. 60% after 12 months. Tolterodine (6 studies): 13%; 56% 57.2%; 49% after 3 months; 70% after 6 months; 45.1% after 12 months (all women) Trospium (2 studies): 35.6%; 20.5% after 3 months (all women) Mirabegron (2 studies): 47.1% after 3 months. One study reported the cure rate for 50 and 100 mg: 43.4% vs. 45.8% (alle women)	*Conclusion* No clear conclusion was written about the use of medication treating UI. Many individuals were not cured and hence may continue to rely on containment. No studies were found assessing success of containment strategies *Remarks* - Only data about UI was reported in this data extraction sheet. - Not for all types of UI data was reported regarding medication treatment - Only cure rates due to medication were reported in this data extraction sheet - Little information about the included articles - No comparison group *Results of AMSTAR* - In-exclusion criteria and PICO (no) - Statement of pre-defined protocol (partial yes) - Comprehensive literature study (partial yes) - Study selection in duplicate (yes) - Data extraction in duplicate (yes) - List of excluded articles (no) - Included studies described in adequate detail (partial yes) - Risk of bias assessment (yes) - Meta-analyse: NA - Conflict of interest (yes)

MUI Solifenacin (2 studies): after 3 months: 26.5% in male; after 12 months a cure rate of 52% in female	

CI: confidence interval; FI: fecal incontinence; MA: meta-analysis; Mg: milligram; MUI: mixed urine incontinence; NA: not applicable; RCT: randomised controlled trail; SLR: systematic literature review; SUI: stress urine incontinence; UUI: urgence urine incontinence

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints

Samuelsson-2015 Geriatrics & Gerontology International Worldwide	To systematically review the efficacy of pharmacological treatment for UI in the elderly and frail elderly.	*Type of incontinence* Urinary incontinence; urgency urinary incontinence; mixed urinary Incontinence; overactive bladder *Intervention* ***Anticholinergic drugs vs placebo*** - Oxybutynin - Tolterodine - Fesoterodine - Solifenacin - Darifenacin - Trospium ***Serotonin–norepinephrine reuptake inhibitor*** - Duloxetine	*Inclusion criteria* • All RCTs and prospective controlled observational studies of pharmacological treatment for urinary incontinence • Patients aged 65 years or older with urinary incontinence (elderly) • Patients living in nursing homes (frail elderly) • At least 20 patients in the intervention group and 20 in the control group • Treatment with placebo or other specified treatment *Exclusion criteria* • Outdated treatments (not specified)	*Search strategy* PubMed (NLM), EMBASE (Elsevier), Cochrane Library (Wiley) and Cinahl (EBSCO); Articles published till 3 October 2013 Search strategy was reported in the supplement; Additionally, reference lists, books and websites were used to identify further studies. PRISMA flow-chart was reported in the article. *Numbers of included articles* **SLR:** 15 articles of which 13 moderate to high quality (all RCTs) **Meta analysis:** 4 articles (3180 participants) *Study endpoints* - Urinary leakage (4 studies; 3180 participants) - Absolute decrease in number of incontinence episodes (6 studies; no MA) - Quality of life (OAB questionnaire; Kings Health Questionnaire; 3 studies; no MA) - Adverse events (12 studies; no MA)
Results				Conclusion and Remarks
Urgency Urinary Incontinence in frail elderly *Oxybutynin vs placebo* Urinary leakage: no statistical effect was found compared to the placebo **Urgency Urinary Incontinence in elderly (based on network meta-analyse)** *Overall anticholinergic drugs vs placebo:* Urinary leakage: significant effect on the frequency of urinary leakage was found compared to the placebo[mean difference: -0.24; 95% CI: -0.32- -0.15] *Fesoterodine vs placebo*				*Conclusion* Anticholinergic drugs have a small, but significant, effect on urinary leakage in the elderly with urgency urinary incontinence. Adverse effects, such as dry mouth and constipation, were common, but none of the studies included a thorough assessment of cognition. Treatment with anticholinergics for UUI in the frail elderly is not evidence based. Further studies are required to evaluate the effects of duloxetine, mirabegron and estrogen in the elderly population. *Remarks* - Only data from the moderate to high quality studies were included in the results section of the article - Not for all interventions, the same study endpoints were found. - The safety results can be found in the article - Small studies included. - Several kinds of UI included

Urinary leakage: significant effect on the frequency of urinary leakage was found compared to the placebo[mean difference: -0.25; 95% CI: -0.35- -0.06]
 	
Absolute decrease in number of incontinence episodes: statistically decrease in number of episodes compared to placebo in 65-74 years; not significant in the 75+ category
 	
Quality of life: the OAB questionnaire improved significantly compared to the placebo
 	
Solfenacin vs placebo
 	
Urinary leakage: significant effect on the frequency of urinary leakage was found compared to the placebo[mean difference: -0.32; 95% CI: -0.46- -0.18]
 	
Absolute decrease in number of incontinence episodes: statistically decrease in number of episodes compared to placebo
 	
Tolterodine vs placebo
 	
Urinary leakage: No significant effect on the frequency of urinary leakage was found compared to the placebo[mean difference: -0.18; 95% CI: -0.35- -0.00]
 	
Absolute decrease in number of incontinence episodes: statistically decrease in number of episodes compared to placebo
 	
Trospium vs placebo
 	
Urinary leakage: significant effect on the frequency of urinary leakage was found compared to the placebo[mean difference: -0.39; 95% CI: -0.32- -0.15]
 	
Quality of life: the Kings health questionnaire improved compared to the placebo (not significant)
 	
Absolute decrease in number of incontinence episodes: statistically decrease in number of episodes compared to placebo
 	
Darifenacin vs placebo
 	
Quality of life: the OAB questionnaire improved significantly compared to the placebo
 	
Absolute decrease in number of incontinence episodes: statistically decrease in number of episodes compared to placebo
 	
Oxybutynin vs placebo
	Results of AMSTAR
	- In-exclusion criteria and PICO (yes)
	- Statement of pre-defined protocol (no)
	- Comprehensive literature study (partial yes)
	- Study selection in duplicate (yes)
	- Data extraction in duplicate (no)
	- List of excluded articles (partial yes)
	- Included studies described in adequate detail (partial yes)
	- Risk of bias assessment (yes)
	- Meta-analyse:
	  ○ Appropriate methods for statical combination (yes)
	  ○ Impact of RoB (yes)
	  ○ Heterogeneity (no)
	  ○ Publication bias (no)
	- Conflict of interest (no)

<u>Absolute decrease in number of incontinence episodes:</u> Decrease in number of episodes compared to placebo (not significant) *Duloxetine vs placebo* Two studies evaluating the effect of duloxetine on SUI were included - There was a significant decrease in the number of urinary leakages in the treatment group compared with placebo (duloxetine: −11.7 urinary leakage episodes per week compared with placebo: −6.9, P = 0.0010). However, when only patients with SUI were analyzed, no effect on urinary leakage was found. - The other study showed no effects on the number of urinary leakages (duloxetine: −6.6 urinary leakage episodes per week compared with placebo: −3.6, P = 0.052).	

CI: confidence interval; MA: meta-analysis; OAB: overactive bladder; RCT: randomised controlled trial; RoB: risk of bias; UI: urinary incontinent; UUI: Urgency Urinary Incontinence

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints

Wani-2021 Current urology Worldwide SLR; no meta-analysis was performed	To compare antimuscarinics with beta adrenergic agonists (mirabegron) in treatment of overactive bladder	*Type of incontinence* Overactive bladder *Intervention* Anticholinergic medications vs. Beta-adrenergic agonists (mirabegron) Antimuscarinics: Oxybutynin, Tolterodine, Propiverine, Trospium, Solifenacin	*Inclusion criteria* • Across the globe • Included all relevant age groups • Both sexes • All important aspects of these two groups of drugs in treatment of OAB have been evaluated. *Exclusion criteria* • Not specified	*Search strategy* Medline, EMBASE (Elsevier), google scholar; Articles published between 2015 to 2020; PRISMA flow-chart was reported in the article. *Numbers of included articles* **SLR:** 20 articles (7 SLRs; 6 retrospective cohort studies; 3 prospective studies; 2 RCTs; 2 cross-sectional) **Meta analysis:** NA *Study endpoints* **Efficiency**: not further specified (9 studies) **Adverse events** (5 studies) **Persistence and adherence** (5 studies) **Cost effectiveness** (3 studies) **Tolerability**: not further specified (3 studies)
Results				Conclusion and Remarks

Efficacy results: Results from all the studies concluded that mirabegron is as efficacious as any other anticholinergic. It has been found to decrease even postvoid residual urine. *Adverse events:* Five studies compared adverse effects. They revealed that mirabegron has less side effects as compared to antimuscarnics. Dry mouth as an adverse effect with mirabegron is that of a placebo. *Persistence and adherence:* Five studies have found that persistence as well as adherence is better with mirabegron (including median as well as yearly persistence/adherence). *Tolerability:* Three studies established that mirabegron has better tolerability as compared to antimuscarnics. It has been found tolerable even in elderly as compared to antimuscarnics. *Combination of antimuscarinics and mirabegron*: Two recent research works have found that combination is providing better results. Most studies have found mirabegron and solifenacin as an excellent combination.	*Conclusion* To conclude, the study found mirabegron is as efficacious as any other antimuscarinics, has better tolerability (including elderly), has better adverse effect profile, is cost effective, has better persistence and adherence rates at 12 months. *Remarks* - Limited information regarding the methods - Results were not presented in detail - No risk of bias was performed for the individual studies *Results of AMSTAR* - In-exclusion criteria and PICO (no) - Statement of pre-defined protocol (no) - Comprehensive literature study (partial yes) - Study selection in duplicate (no) - Data extraction in duplicate (no) - List of excluded articles (no) - Included studies described in adequate detail (no) - Risk of bias assessment (no) - Meta-analyse: NA - Conflict of interest (yes, no conflict)

NA: not applicable; OAB: overactive bladder; RCT: randomised controlled trial; RoB: risk of bias; SLR: systematic literature review

Author, Year, (Country)	Objective/Aims	Study type	Setting Population Sample size Age	Eligibility criteria	Condition/ Symptoms	Drug class: type	Groups/Interventions N/group	Outcome measures & Assessment tools	Time of outcome assessment
Burgio et al., 2020 (USA)	To determine whether combining behavioural and drug therapies improve outcomes compared with each therapy alone for OAB in men and to compare 3 sequences for implementing combined therapy	3-site, 2-stage, 3-arm, parallel-group randomized clinical trial	***Setting*** Outpatient clinic ***Population*** Community-dwelling men ≥40yrs ***Sample size*** N = 432 (enrolled) N = 204 (randomised) N= 204 (included in ITT analyses) ***Age, mean (SD)*** Gr B: 63.6 (10.9) Gr D: 65.5 (11.0) Gr B+D: 63.2 (11.6)	***Inclusion*** ≥ 9 voids/24 on 7-day baseline bladder diary ***Exclusion*** indicators of outlet obstruction, positive dementia screening, and medical conditions that could have been contributing to urinary symptoms (e.g., DM, UTI, cancer or neurological conditions)	OAB: urgency and frequency ± UUI	**Antimuscarinic**: tolterodine **α-blocker**: tamsulosin	Behavioural treatment (n= 71) **vs** antimuscarinic+ α-blocker: tolterodine 4 mg + tamsulosin 0.4 mg daily (n=68) **vs** behavioural treatment + antimuscarinic + α-blocker (n=65)	***Primary outcomes*** Changes in voiding frequency ***Secondary + other outcomes*** ○ Changes in urgency, incontinence, and nocturia ○ Change from baseline in OAB-q and IPSS. ***Assessment tools*** ○ 7-day bladder diary ○ 24h frequency/volume log ○ OAB-q ○ IPSS ○ PSQEPI and GPoI	6 Weeks 12 weeks
Results (Intent-to-treat analyses)								**Conclusion and Remarks**	
At 6-weeks FUP ***Primary outcome:*** ○ Mean (SD) voids per 24 hours decreased significantly in all 3 groups from baseline to 6-week follow-up (behavioural therapy: 11.7 [2.4] vs 8.8 [2.1]; change, 2.9 [2.4]; percentage change,24.7%; P < .001; drug therapy: 11.8 [2.5] vs 10.3 [2.7]; change, 1.5 [2.3]; percentage change, 12.7%; P < .001; combined therapy: 11.8 [2.4] vs 8.2 [2.3]; change, 3.6 [2.1]; percentage change, 30.5%; P < .001). Intention-to-treat analyses								***Main conclusions*** Combining behavioural and drug therapy yields greater improvements in OAB symptoms than drug therapy alone but not behavioural therapy alone. When	

indicated that posttreatment mean (SD) voiding frequencies were significantly lower in those receiving combined therapy compared with drug therapy alone (8.2 [2.3] vs 10.3 [2.7]; P < .001) but not significantly lower compared with those receiving behavioural therapy alone (8.2 [2.3] vs 8.8 [2.1]; P = .19) and were lower for behavioural therapy alone compared with drug therapy alone (8.8 [2.1] vs 10.3 [2.7]; P < .001). ***Secondary + other outcomes*** ○ Mean frequency of nocturia decreased significantly in all 3 groups. Analysis of covariance indicated significant between-group differences in favour of combined therapy, with drug therapy alone showing the smallest changes (mean [SD]: behavioural therapy alone, 1.3 [0.8]; drug therapy alone, 1.8 [1.2]; combined therapy, 1.3 [1.0]; P < .001). ○ Mean urgency scores decreased significantly in the combined therapy group but not in the behavioural therapy alone or drug therapy alone groups. ○ Scores on the OAB-q decreased significantly. Analysis of covariance yielded significant group differences, with combined therapy being superior (mean [SD] Overactive Bladder Questionnaire score: behavioural therapy alone, 43.0[28.2]; drug therapy alone, 39.5 [30.0]; combined therapy, 23.8 [22.1]; P < .001; mean [SD] ○ Scores on the IPSS decreased significantly. Analysis of covariance yielded significant group differences behavioural therapy alone, 11.4 [5.3]; drug therapy alone, 11.5 [5.8]; combined therapy, 9.2 [4.8]; P < .001) **At 12-weeks FUP** ***Primary outcome:*** ○ At 12-week follow-up, after all groups had received combined therapy, improvements in mean (SD) voids per 24 hours were also greatest for those receiving initial combined therapy compared with baseline (behavioural therapy: 11.7 [2.4] vs 8.0 [2.2]; change, 3.7 [2.3]; percentage change, 31.6%; P < .001; drug therapy: 11.8 [2.5] vs 8.6 [2.3]; change, 3.2 [2.5]; percentage change, 27.1%; P < .001; combined therapy: 11.8 [2.4] vs 8.0 [2.2]; change, 3.8 [2.1]; percentage change, 32.2%; P < .001), but there were no statistically significant group differences on primary or secondary measures. ***Secondary + other outcomes*** ○ At 12-week follow-up, improvements were greatest in the combined therapy group but without between-group differences on the other bladder diary and questionnaire measures	using a stepped approach, it is reasonable to begin with behavioural therapy alone. ***Remarks*** Limitations: ○ No blinding of participants and interventionists ○ Each stage of therapy was 6 weeks in duration (rationale for choosing 6 weeks was based on previous work showing a flattening of symptom improvement curves after 4-6wks with drug therapy)

Abbreviations: DM: diabetes mellitus; UTI: urinary tract infection; UUI: urgency urine incontinence; OAB: overactive bladder; OAB-q: overactive bladder questionnaire (To measure symptom bother and condition-specific health-related quality of life); IPSS (to measure frequency of LUTs): International Prostate Symptom Score; PSQEPI: Patient Satisfaction Question, Estimate Percent Improvement; GPoI: Global Perception of Improvement (to assess patients' perceptions of treatment outcomes); ITT: intention-to-treat analyses; FUP: Follow-up; Gr: group; B: behavioural group; D: drugs group; B+D: Behavioural and drugs

Author, Year, (Country)	Objective/Aims	Study type	Setting Population Sample size Age	Eligibility criteria	Condition/ Symptoms	Drug class: type	Groups/Interventions N/group	Outcome measures & Assessment tools	Time of outcome assessment
Huang et al. 2020 (Taiwan)	To investigate the differences in clinical characteristics and manifestations between different medication groups using real-world data	Retrospective single-centre study	***Setting*** Health care institute ***Population*** Men ≥ 18yrs ***Sample size*** (N = 215) ***Age mean (SD)*** Gr A: 69.3 ± 15.2 Gr B: 77.4 ± 12.6 Gr C: 68.7 ± 14.1	***Inclusion*** Diagnosis of OAB proposed by the ICS ***Exclusion*** Patients with neurogenic bladder and cancer of the genitourinary tract	OAB: urgency and frequency ± UUI, nocturia	**Antimuscarinics:** oxybutynin; solifenacin; tolterodine **β3-adrenoceptor agonist:** Mirabegron	***Groups/interventions*** Antimuscarinics **vs** Mirabegron ***N/group*** Gr A: oxybutynin 5 mg, solifenacin 5 mg, tolterodine 4 mg (n=43) Gr B: Mirabegron 25mg (n=35) Gr C: discontinued treatment (n=137)	***Primary outcomes*** Changes in voiding frequency ***Secondary +other outcomes*** Changes in urgency, incontinence, and nocturia; Change from baseline in OAB-q and IPSS ***Assessment tools*** Urodynamics studies, OABSS, CGI, QoL-q.	NR
Results (Intent-to-treat analyses)								**Conclusion and Remarks**	
Results of urodynamic studies No significant group differences in any of the urodynamic parameters except for CMG capacity (Table 1). Group A had a significantly larger CMG capacity (mean ± SD, 257.3 ± 135.1 cm3, range 89–497 cm3) than group B (125.8 ± 46.0 cm3, range 76–189 cm3, p = 0.002) and group C (170.5 ± 99.2 cm3, range 86–425 cm3, p = 0.001).								***Main conclusions*** Patients who kept antimuscarinics and the beta-3 adrenoceptor agonist showed better treatment outcomes compared to the discontinued group. There was no significant difference in	

Table 1: Comparison of urodynamic parameters of patients in each treatment group.

	Antimuscarinics (n = 43)	Beta-3 agonist (n = 35)	Group C Discontinued (n = 137)	P
First desire capacity (ml)	127.3 ± 82.1	85.6 ± 32.1	105.0 ± 72.0	0.277
CMG capacity (ml)	257.3 ± 135.	125.8 ± 46.0	170.5 ± 99.2	0.01*
Pdet at Qmax (cm H2O)	48.2 ± 21.8	52.9 ± 33.9	50.9 ± 26.2	0.877
Qmax (ml/s)	19.0 ± 12.6	13.1 ± 7.6	15.4 ± 10.2	0.079
PVR (ml)	54.6 ± 106.4	25.7 ± 31.5	39.1 ± 59.6	0.442

Medication group A consisted of antimuscarinic-naïve individuals (n = 35) and those who had discontinued mirabegron treatment (n = 8); the CMG capacity of each subgroup was 260.9 ± 119.2 cm3 (n = 35) and 243.2 ± 102.6 cm3s (n = 8), p = 0.7, respectively

Group B comprised mirabegron-naïve patients (n = 30) and those who had discontinued antimuscarinic treatment (n = 5); the CMG capacity of each subgroup was 123.1 ± 43.6 (n = 30) and 142 ± 53.8 (n = 5), p = 0.87, respectively.

Results of OABSS, QoL and CIG outcomes

Significant differences were noted in the OABSS in group A (median 4, range − 1 to 11) and group B (median 4, range − 2 to 11) after treatment. Compared to group C (median 2, range − 8 to 11), the OABSS total in both groups A and B significantly improved after medication (p = 0.002 and p = 0.006, respectively).Figure 1.

Both treatment groups showed better responses on the QoL and the CGI questionnaires after treatment, showing that both antimuscarinics and beta-3 adrenoceptor agonists were effective medications. Figure 2

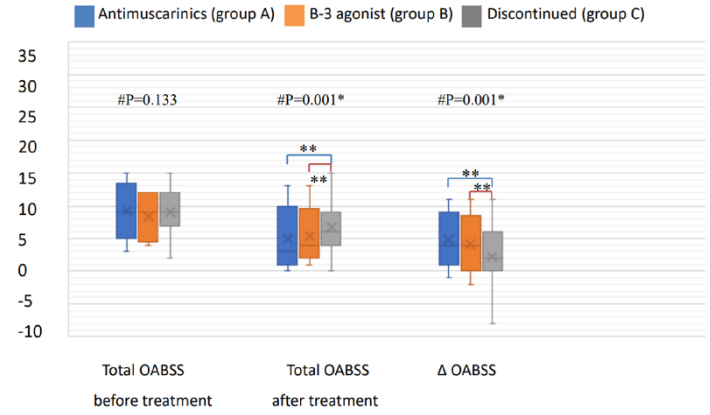
the treatment outcome between the two pharmacotherapies.

Remarks

Limitations

- Excluded patients who received combination therapy with mirabegron + an antimuscarinic agent
- Did not consider escalations in the dose of pharmacotherapy
- No voiding diaries and image surveys were applied
- Retrospective and single-centre study; thus, further studies needed to validate the results

Figure 1. Comparison of OABSS questionnaire results in the three groups



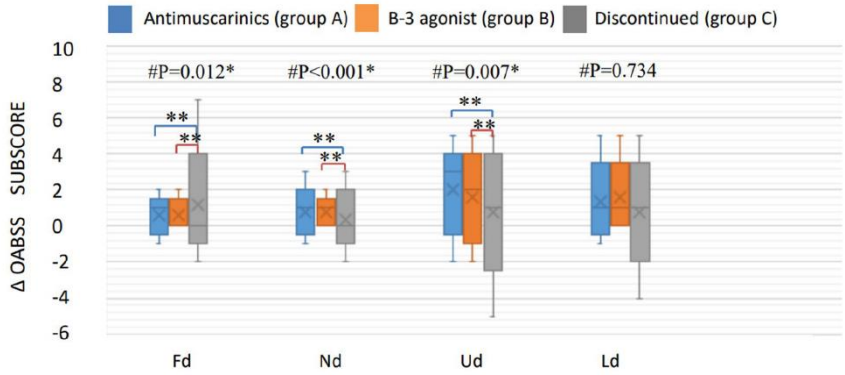


Figure 2. The differentiation of OABSS questionnaire subscores in the three groups

*Significant if $p < 0.05$.

Abbreviations: Fd: differentiation of daytime frequency score; Nd: differentiation of night-time frequency score; Ud: differentiation of urgency score; Ld: differentiation of urgency incontinence score; CMG: cytometric capacity; PVR: Postvoid residual; UUI: urgency urine incontinence; OABSS: Overactive Bladder Symptom Score; CGI: Clinical Global Impression; QoL-q: Quality of life questionnaire; ICS: International Continence Society; OAB: overactive bladder; Gr: Group

Author, Year, (Country)	Objective/ Aims	Study type	Setting Population Sample size Age	Eligibility criteria	Condition/ Symptoms	Drug class: type	Groups/ Interventions N/group	Outcome measures & Assessment tools	Time of outcome assessment
Komesu et al, 2020 (USA)	To evaluate hypnotherapy's efficacy compared to medications in treating women with UUI	Randomised, parallel-group, single-institution, noninferiority trial	***Setting*** Academic centre ***Population*** Women ≥ 18yrs of age ***Sample size*** N = 165 (consented) N = 152 (randomised) N = 142 (included in analyses) ***Age mean (SD)*** Gr Hypnotherapy: 57.6 (12.77) Gr Pharmacotherapy: 59.5 (10.30)	***Inclusion*** moderate to severe UUI defined as ≥5 urgency urinary incontinence episodes on a 3-day prospective bladder diary ***Exclusion*** Women with: ○ History of neurologic diseases such as Multiple Sclerosis, Parkinson's disease, stroke, or dementia ○ History of schizophrenia or untreated bipolar disorder or current drug or alcohol dependence ○ Those who have taken anti-cholinergic medications for UUI within the last 3 weeks (women who have taken anti-cholinergic for UUI but discontinued them > than 3 weeks ago may participate in the study) or have a sacral neuromodulator in place to treat UUI or have received onabotulinum toxin A in the last 12 months to treat UUI.	UUI	Antimuscarinic: ER oxybutynin, ER tolterodine	Hypnotherapy (n=70) **vs** pharmacotherapy ER oxybutynin 10mg/daily or ER tolterodine 4mg/day (n=72)	***Primary outcome*** Difference between-groups' of percent change in UUIE on a 3-day bladder diary at 2 months ***Secondary outcomes*** Difference between-groups' of percent change in UUIE at 6 and 12 months. ***Assessment tools*** OABq-SF, PPBC, ISI, PISQ-12.	2,6 and 12 months

				○ Contraindications to anti-cholinergic medications (untreated narrow-angle glaucoma, significant urinary retention or gastric retention) ○ Pregnant women or lactating women, women who plan to become pregnant in the next year, or premenopausal women unwilling to use contraception if engaging in sexual relations during the year of study participation (hysterectomy is considered to be a form of contraception) ○ Untreated urinary tract infection ○ Prolapse which extends past the hymen (POP-Q points of ≥ 1+) which may be responsible for UUI ○ who cannot keep the majority of the study therapy appointments or those without reliable contact phone numbers or methods of communication with the study personnel.					

Results	**Conclusion and Remarks**
Primary outcome Baseline UUIE medians were similar for both groups (hypnotherapy 8 (4-14) vs pharmacotherapy 7 (4-11). For 2-month UUIE, the noninferiority of hypnotherapy was not provided. Although the median % changed from baseline, comparing hypnotherapy and medication was 0% 95% IC (-16.7% to 0.0%). The UUIE secondary outcomes at 6 and 12 months showed hypnotherapy to be noninferior to medications. Table 2.	***Main conclusions*** Both hypnotherapy and medications were associated with substantially improved urgency urinary incontinence at all follow-up. Hypnotherapy proved noninferior to medications at longer-term follow-up of 6 and 12 months. Hypnotherapy is a

Table 1. Intent-to-treat comparison

	Hypnotherapy (median UUI episodes)	**Pharmacotherapy (median UUI episodes)**
Baseline UUI (n=142)		
N	70	72
Median UUI episodes (Q1,Q3) - primary outcome	8 (4-14)	7 (4-11)
2 mo UUI (n=142)		
N	70	72
Median UUI episodes (Q1, Q3)	2 (0-6)	1 (0-3)
Median % change (95% CI)	73.0% (60.0 - 88.9%)	88.6% (78.6 -100.0%)
6 mo UUI (n=138)		
N	67	71
Median UUI episodes (Q1, Q3)	1 (0-4)	1 (0-4)
Median % change (95% CI)	85.7% (75-100%)	83,3% (64.7-100%)
12 mo UUI (n=140)		
N	69	71
Median UUI episodes (Q1, Q3)	1 (0-3)	1 (0-6)
Median % change (95% CI)	85.7 (66.7 – 94.4%)	80% (54.5 – 100%)

Exploratory secondary outcomes

promising, alternative treatment for women with UUI.

Clinical implication

- Both groups were associated with >70% decrease in UUIE (point at which women report enhanced QoL and treatment satisfaction
- >3/4 women maintained the meaningful change for 12 months
- Secondary outcomes (questionnaires, diary date and per-protocol analysis) supported the comparative effectiveness of the treatments (participants in both groups experienced similar improvement at all time points
- Exploratory repeated-measures suggest that hypnotic susceptibility affected the results for both intervention
    - Both treatments were associated with improved UUIEs in medium and high-hypnotic susceptibility participants
    - Among low hypnotic-susceptible participants, trends in UUI improvement favoured medication suggesting that hypnotherapy may be less efficacious in this subgroup

Remarks

Limitations

- Participants were not masked to treatment, potentially biasing treatment results.

Results of quality check

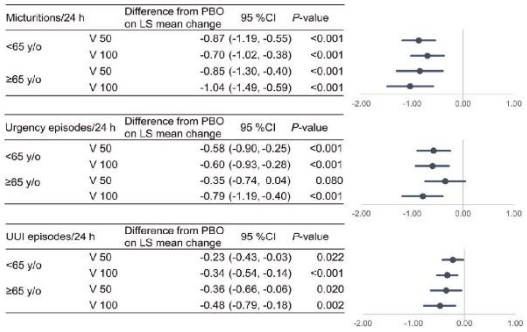
Per protocol analysis found hypnotherapy to be noninferior in reduction of UUIEs at 2, 6 and 12 months. There were no differences between groups regarding questionnaire results when adjusted for baseline Adjusted results (i.e., controlling for baseline UUIE) suggested that change in UUIE between groups differed at various time points and depended on participants 'hypnotic susceptibility ○ At 6 months, among medium hypnotic participants, hypnotherapy was superior to medication ○ At 12 months, among high-hypnotic susceptibility participants, hypnotherapy was superior to medication ○ In medium and high hypnotic participants, UUIE improved between 2 and 12 months in the hypnotherapy groups but worsened in medication group Adverse events Of the 152 randomised, 62 (41%) reported at least 1 AE (25 in hypnotherapy group, 34 in medication group). Medication participants reported aniticpated AEs 12times. Both groups reported the following AEs: UTI (6 medication, 5 hypnotherapy), falls (5 medication, 3 hypnotherapy), backpain (4 medication, 3 hypnotherapy). Four serious AEs (3 medication, 1 hypnotherapy) occurred, likely unrelated to treatment (hospitalisation for pre-existing disease 3; fall while horse-riding 1).	○ No blinding

Abbreviations: FR: extended-release; OABq-SF: Overactive Bladder Short form questionnaire; PPBC: Patient Perception of Bladder Condition; ISI: Incontinence Severity Index; PISQ: Prolapse and Incontinence Sexual Questionnaire Short Form; mo: months

Author, Year, (Country)	**Objective/Aims**	**Study type**	**Setting** **Population** **Sample size** **Age**	**Eligibility criteria**	**Condition/** **Symptoms**	**Drug class: type**	**Groups/ Interventions** **N/group**	**Outcome measures & Assessment tools**	**Time of outcome assessment**
Yoshida et al., 2021 (Japan)	To examine the safety and efficacy of vibrion in patients aged ≥65 years, with a focus on the effects on cardiovascular	Post-hoc analyses of a randomised, placebo-controlled, double-blind comparative phase 3 study	**Setting** Not clearly reported - 109 sites ***Population*** Male/female aged ≥20yr	***Inclusion*** OAB patients with ≥8 micturition/day and either ≥1 urgency episodes/day or ≥1 UI episodes/day	OAB: urgency and frequency ± UUI	**β3-AR agonist**: Vibegron	PBO **vs** V50 **vs** V100 <65yrs (n=716) ○ PBO: n=238 ○ V50: n=239 ○ V100: n=239 >65 years	***Primary outcomes (for efficacy analysis)*** mean micturition/d at week 12 from baseline. ***Secondary outcomes*** Daily mean micturition, urgency episodes, UUI	12 weeks

	system and OAB		Females accounted for approx. 90% of all subjects ***Sample size*** N = 1232 (randomised) N = 1108 (included in subgroup analysis by age) N= 715 (Efficacy studied in FAS) ***Age mean (SD)*** <65yrs (n=716) mean age approx. 51yr – PBO: 51.8 (7.8) – V50: 50.9 (7.9) – V100: 51.8 (6.9) ≥65 years (n=392), mean age approx. 71yr – PBO: 71.7 (4.8) – V50: 70.9 (4.4) – V100: 71.2 (4.6)	***Exclusion*** UTI, bladder cancer, bladder calculus, interstitial cystitis, enlarged prostate, residual urinary volume >100 ml, and systolic blood pressure (SBP) ≥ 160 mmHg, diastolic blood pressure (DBP) ≥ 100 mmHg, or pulse rate ≥110 bpm were excluded from the study.			○ PBO: n=131 ○ V50: n=131 ○ V100: n=130	episodes, UI episodes, Voided volume/micturition. ***Assessment tools*** 3-d micturition diary, KHQ.	
Results							**Conclusion and Remarks**		
The results showed a significant change versus placebo in the number of micturition, number of urgency episodes and the number of UUI episodes in the V50 and V100 groups. No significant differences was found for urgency episodes in the V50 group aged ≥65 years (Figure 3).							***Main conclusions*** V50/100 demonstrated similar efficacy in the <65-year and ≥65-year subgroups; an increasing trend in the voided volume/ micturition was observed in subjects aged ≥65 years compared to subjects aged <65 years. The post-hoc analysis suggest that vibegron exerts its efficacy on OAB symptoms with minimal		

Figure 3. Differences versus placebo group from baseline to week 12.



Micturitions/24 h		Difference from PBO on LS mean change	95 %CI	*P*-value
<65 y/o	V 50	-0.87	(-1.19, -0.55)	<0.001
	V 100	-0.70	(-1.02, -0.38)	<0.001
≥65 y/o	V 50	-0.85	(-1.30, -0.40)	<0.001
	V 100	-1.04	(-1.49, -0.59)	<0.001

Urgency episodes/24 h		Difference from PBO on LS mean change	95 %CI	*P*-value
<65 y/o	V 50	-0.58	(-0.90, -0.25)	<0.001
	V 100	-0.60	(-0.93, -0.28)	<0.001
≥65 y/o	V 50	-0.35	(-0.74, 0.04)	0.080
	V 100	-0.79	(-1.19, -0.40)	<0.001

UUI episodes/24 h		Difference from PBO on LS mean change	95 %CI	*P*-value
<65 y/o	V 50	-0.23	(-0.43, -0.03)	0.022
	V 100	-0.34	(-0.54, -0.14)	<0.001
≥65 y/o	V 50	-0.36	(-0.66, -0.06)	0.020
	V 100	-0.48	(-0.79, -0.18)	0.002

Differences (95% CI) versus placebo group in LS mean change from baseline to week 12 in the voided volume/micturition in the V50 and V100 groups demonstrating a significant difference between the two vibegron groups vs. placebo:

- **20.9 (13.7, 28.1) and 16.3 (9.2, 23.5) in the <65-year subgroup**
- **34.8 (25.4, 44.1) and 32.5 (23.1, 41.9) ml in the ≥65-year subgroup**

The LS mean change in the ≥65-year subgroup was approximately 10 ml greater than that in the <65-year subgroup in both the V50 and V100 groups (Figure 4).

influence on cardiovascular parameters in both patients aged ≥65 and <65 years, suggesting that vibegron may be useful in OAB treatment regardless of age.

Limitations

- 90% of subjects were female thus issue with generalizability of findings
- No elderly subjects aged ≥75 years were included
- Post-hoc analysis of a study with FUP of 12 weeks
- Further studies on efficacy of vibegron in patients aged ≥65 years, including male patients with longer-term needed

Results of quality check

- The difference in the change between V50 and V100 groups may have been influenced by the baseline duration of OAB in the <65-year subgroup, and by the baseline average voided volume/micturition in the ≥65-year subgroup
- Impact of comorbidities and interaction with other medications should be considered in the practice of OAB in older population.

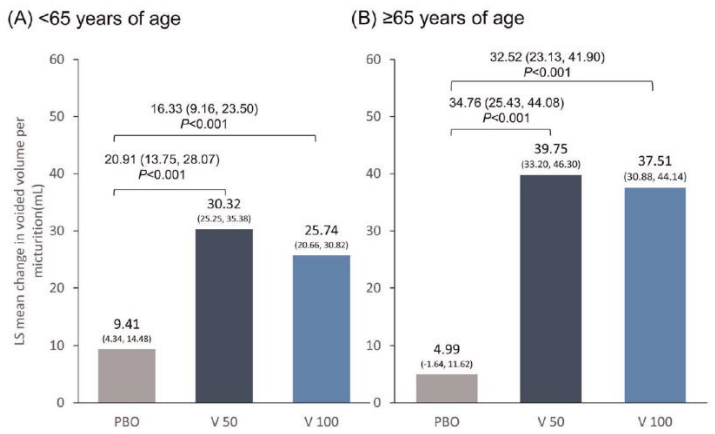


Figure 4. LS mean changes from baseline to week 12 in voided volume/micturition

Abbreviations: PBO: placebo; V50: Vibegron 50mg; V100: Vibegron 100mg; FAS: full analysis set; UUI: urgency urine incontinence; UI: urine incontinence; OAB: Overactive bladder; KHG: King's Health questionnaire; LS; mean change from baseline to week 12

Author, Year, (Country)	Objective/Aims	Study type	Setting Population Sample size Age	Eligibility criteria	Condition/ Symptoms	Drug class: type	Groups/Interventions N/group	Outcome measures & Assessment tools	Time of outcome assessment
Zachariou et al., 2021 (Greece)	To evaluate the impact of mirabegron's treatment on the degree of burden experienced by caregivers of elderly female patients with UI	Pre-post pilot study	***Setting*** Urban area ***Population*** Convenience sample of caregivers + their female patients with UUI/MUI ***Sample size*** N = 224 caregivers/patients (enrolled) N = 186 (analysed) ***Mean age (SD)*** ○ Group A (control): 73 (13) ○ Group B (intervention): 73.5 (14)	***Inclusion*** MMSE score >24 or more, absence of cognitive impairment or dementia, willingness/ability to engage in study procedures and Greek language fluency ***Exclusion*** Terminal ness (life expectancy less than a year), unable to walk with help to reach and use the toilet, or presented UTI	Urinary incontinence	**β3-AR agonist**: Mirabegron	No treatment vs Mirabegron Group A (control): n=91 Group B (50mg Mirabegron): n=95	**Outcomes** i.e. pre-and post episodes of : ○ Voiding frequency and volume ○ Nocturia ○ urgency episodes ○ UI episodes ○ # of incontinence pads ***Assessment tools*** 3-day micturition diary	3 months

Results	Conclusion and remarks
Patients receiving mirabegron presented a statistically significant improvement in UI parameters. 20% of participants in Group B that were incontinent at primary evaluation became continent by the study endpoint. **Table 2. Urinary Parameters of the Older Female Patients (P<0.05)**	***Main conclusion*** Mirabegron administration can improve the quality of life of older females suffering from UI while substantially relieving caregiver burden. ***Remarks*** **Limitation** o Non-random sampling method used o Deliberate and non-random convenience sample o Self-assessment question thus issues related to validity and reliability of responses ***Results of quality check*** o Exclusion criteria might introduce bias o No random/consecutive participants o Group A + C suffering from various medical conditions (stroke, post-operative recovery, Parkinson etc). o No remark on intent-to-treat analyses o Initial 3 months treatment with drug o Type of analysis used

Group A Control	Pre-Observation	Post-Observation	*P* value
Frequency	11.0 (1.0)	11.0 (1.0)	0.284
Urgency episodes	6.5 (1.0)	7.0 (1.0)	0.113
Nocturia episodes	2.5 (1.0)	2.0 (1.0)	0.262
Incontinence episodes	3.0 (1.0)	3.0 (2.0)	0.374
Incontinence pads	5.0 (2.0)	5.0 (2.0)	0.341
Voided volume (mL)	124.5 (31.0)	116.0 (27.0)	0.101
Group B Mirabegron	**Pre-Treatment**	**Post-Treatment**	***P* value**
Frequency	11.0 (2.0)	8.0 (2.0)	<0.001
Urgency episodes	7.0 (2.0)	4.0 (2.0)	<0.001
Nocturia	3.0 (1.0)	2.0 (1.0)	<0.001
Incontinence episodes	3.0 (1.0)	1.0 (1.0)	<0.001
Incontinence pads	4.0 (2.0)	2.0 (2.0)	<0.001
Voided volume (mL)	111.0 (33.0)	157.0 (26.0)	<0.001

Abbreviations: UTI: urinary tract infection; MMSE: Mini-Mental State Examination, UI: urinary incontinence

Verantwoording Uitgangsvraag 4- Interventies voor fecale incontinentie

Literatuursearch en selectie

Systematisch literatuuronderzoek is uitgevoerd in het jaar 2023 (d.d: 10-02-2023). Er is gezocht in drie databases: Medline (via Pubmed), Embase en Cinahl.

Volgens de AQUA-leidraad is elke uitgangsvraag vertaald in een PICO vraag, die het probleem of patiënt/populatie (P), de interventie (I), de vergelijking (comparison, C) en de gewenste uitkomstmaat (outcome, O) beschrijven. In Tabel 37 staat de PICO-vraag uitgewerkt voor uitgangsvraag 4.

Tabel 37. PICO bij uitgangsvraag interventies bij fecale incontinentie.

P:	Ouderen met fecale incontinentie, gemiddelde leeftijd in populatie ≥60 j
I:	Behandelinterventies zoals: bekkenbodemspiertraining, medicamenteuze behandeling, advies over leefstijl (o.a. overgewicht, vochtinname) en advies over toiletgang
C:	Elke vergelijking (ander soort behandeling/geen behandeling)
O:	Relevante uitkomstmaten: - Ervaren kwaliteit van leven door de zorgvrager (fecal incontinence quality of life questionnaire) - Ervaren gezondheid door de zorgvrager - Ervaren hinder door de zorgvrager als gevolg van fecale incontinentieproblemen - Ervaren verbetering door de zorgvrager - Symptoomscores (incontinence impact questionnaire; urogential distress inventory; Wexner score; Vaizey score; fecal incontinence severity index) - Grootte van de zorgvraag

De PICO-vraag is omgezet in zoektermen die gecombineerd zijn tot een zoekstrategie waarmee de gewenste literatuur geïdentificeerd is.

Tabel 38. Zoekstrategie Pubmed.

Onderwerp	Fecale incontinentie
#1: Incontinentie	“Fecal Incontinence”[Mesh] OR “fecal incontinence”[tiab] OR “Flatus incontinence”[tiab] OR “bowel incontinence”[tiab] OR “anal incontinence”[tiab] OR “feces incontinence”[tiab] OR encopres*[tiab] OR “anus incontinence”[tiab] OR “defecation incontinence”[tiab] OR “feacal incontinence”[tiab]
#2: Studie populatie	"Frail Elderly"[Mesh] OR "Aged, 80 and over"[Mesh] OR frail*[tiab] OR vulnerable[tiab] OR "low functioning"[tiab] OR "functional decline"[tiab] OR aging[tiab] OR ageing[tiab] OR elder*[tiab] OR old[tiab] OR older[tiab] OR geriatric*[tiab] OR "older people"[tiab] OR "community dwelling elderly"[tiab] OR "care home"[tiab] OR “community care”[tiab] OR “nursing care”[tiab] OR nurse[ad] OR nursing[ad]
# 3: Focus van de studies: Behandelinterventies	"Behavior Therapy"[Mesh] OR "Cognitive training"[Mesh] OR "conservative interventions"[tiab] OR "Toilet Training"[Mesh] OR "habit training"[tiab] OR "habit retraining"[tiab] OR "timed voiding"[tiab] OR "prompted voiding"[tiab] OR "Life Style"[Mesh] OR "appliances"[tiab] OR "Patient Education as Topic"[Mesh] OR "continence promotion"[tiab] OR "toileting"[tiab] OR "Fluid Therapy"[Mesh] OR "toilet training"[tiab] OR "physical therapy"[tiab] OR "continence advice"[tiab] OR "functional incidental training"[tiab] OR "urge response"[tiab] OR "Pelvic Floor"[Mesh] OR "pelvic floor muscle"[tiab] OR Biofeedback[tiab] OR treatment[tiab] OR Therapeutics[Mesh] OR "pharmaceutical preparations"[Mesh] OR medication*[tiab] OR "Drug Therapy"[Mesh] OR "drug

	treatment"[Title/Abstract:~3] OR “drug therapies”[Title/Abstract:~3] OR “drug therapy”[Title/Abstract:~3]
#4: Publicatietype	Systematic review[pt] OR systematic review[tiab] OR meta-analysis[pt] OR meta-analysis[tiab] OR meta-analyses[tiab] OR meta analysis[tiab] OR meta analyses[tiab] OR metaanalysis[tiab] OR metaanalyses[tiab] OR randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled[tiab] OR placebo*[tiab] OR trial[tiab] OR intervention[tiab] OR "Cross-Over Studies"[Mesh] OR "Double-Blind Method"[Mesh] OR "Prospective Studies"[Mesh] OR "Follow-up Studies"[Mesh] OR "Cohort Studies"[Mesh] OR crossover[tiab] OR cross-over[tiab] OR double-blind[tiab] OR doubleblind[tiab] OR single-blind[tiab] OR singleblind[tiab] OR cohort*[tiab] OR prospective[tiab] OR longitudinal[tiab] OR observational[tiab] OR follow-up[tiab] OR followup[tiab] OR effectiveness[tiab] OR safety[tiab] OR “clinical review”[tiab] OR “literature review”[tiab]
Limits	Gepubliceerd vanaf 2008
#1 AND #2 AND #3 AND #4 + limits	

Tabel 39. Zoekstrategie in Embase.

Onderwerp	Fecale incontinentie
#1: Incontinentie	‘feces Incontinence’/exp OR ‘fecal incontinence’:ti,ab OR 'Flatus incontinence':ti,ab OR 'bowel incontinence':ti,ab OR 'anal incontinence':ti,ab OR 'feces incontinence':ti,ab OR encopres*:ti,ab OR 'anus incontinence':ti,ab OR 'defecation incontinence':ti,ab OR 'feacal incontinence':ti,ab
#2: Studie populatie	‘Frail Elderly’/exp OR ‘Very elderly’/exp OR frail*:ti,ab OR 'vulnerable’:ti,ab OR ‘low functioning’:ti,ab OR 'functional decline':ti,ab OR aging:ti,ab OR ageing:ti,ab OR elder*:ti,ab OR old:ti,ab OR older:ti,ab OR geriatric*:ti,ab OR 'older people':ti,ab OR 'community dwelling elderly':ti,ab OR 'care home':ti,ab OR 'community care':ti,ab OR 'nursing care':ti,ab OR nurse:ad OR nursing:ad
# 3: Focus van de studies: Behandelinterventies	‘Behavior Therapy’/exp OR ‘Cognitive Training’/exp OR ‘conservative interventions’:ti,ab OR ‘Toilet Training’/exp OR ‘habit training’:ti,ab OR 'habit retraining':ti,ab OR 'timed voiding':ti,ab OR 'prompted voiding':ti,ab OR ‘Lifestyle’/exp OR ‘appliances’:ti,ab OR ‘Patient Education’/exp OR ‘continence promotion’:ti,ab OR ‘toileting’:ti,ab OR ‘Fluid Therapy’/exp OR ‘toilet training’:ti,ab OR ‘physical therapy’:ti,ab OR ‘continence advice’:ti,ab OR ‘functional incidental training’:ti,ab OR ‘urge response’:ti,ab OR ‘Pelvis Floor’/exp OR ‘pelvic floor muscle’:ti,ab OR biofeedback:ti,ab OR treatment:ti,ab OR therapy/exp OR ‘drug’/exp OR ‘drug therapy’/exp OR medic*:ti,ab OR (drug NEAR/3 treatment):ti,ab OR (drug NEAR/3 therapies):ti,ab OR (drug NEAR/3 therapy):ti,ab
#4: Publicatietype	‘Systematic review’/exp OR ‘systematic review’:ti,ab OR ‘meta analysis’/exp OR meta-analysis:ti,ab OR meta-analyses:ti,ab OR 'meta analysis':ti,ab OR 'meta analyses':ti,ab OR metaanalysis:ti,ab OR metaanalyses:ti,ab OR term:it OR term:it OR randomized:ti,ab OR randomised:ti,ab OR RCT:ti,ab OR controlled:ti,ab OR placebo*:ti,ab OR trial:ti,ab OR intervention:ti,ab OR 'Cross-Over Studies'/exp OR 'Double-Blind Method'/exp OR 'Prospective Studies'/exp OR 'Follow-up Studies'/exp OR 'Cohort Studies'/exp OR crossover:ti,ab OR cross-over:ti,ab OR double-blind:ti,ab OR doubleblind:ti,ab OR single-blind:ti,ab OR singleblind:ti,ab OR cohort*:ti,ab OR prospective:ti,ab OR longitudinal:ti,ab OR observational:ti,ab OR follow-up:ti,ab OR followup:ti,ab OR effectiveness:ti,ab OR safety:ti,ab OR ‘clinical review’:ti,ab OR ‘literature review’:ti,ab
Limits	Gepubliceerd vanaf 2008; Article; article in press; review

#1 AND #2 AND #3 AND #4 + limits

Tabel 40. Zoekstrategie CINAHL.

Onderwerp	Fecale incontinentie
#1: Incontinentie	TI (“Flatus incontinence” OR “bowel incontinence” OR “anal incontinence” OR “feces incontinence” OR encopres* OR “anus incontinence” OR “defecation incontinence” OR “feacal incontinence”) OR MH “Fecal Incontinence” OR AB (“Flatus incontinence” OR “bowel incontinence” OR “anal incontinence” OR “feces incontinence” OR encopres* OR “anus incontinence” OR “defecation incontinence” OR “feacal incontinence”)
#2: Studie populatie	TI (Frail* OR vulnerable OR "low functioning" OR "functional decline" OR aging OR ageing OR elder* OR old OR older OR geriatric* OR "older people" OR "community dwelling elderly" OR "care home" OR “community care” OR “nursing care”) OR AB (Frail* OR vulnerable OR "low functioning" OR "functional decline" OR aging OR ageing OR elder* OR old OR older OR geriatric* OR "older people" OR "community dwelling elderly" OR "care home" OR “community care” OR “nursing care”) OR MH ("Frail Elderly" OR "Aged, 80 and over") OR AF ("nurse" OR "nursing")
# 3: Focus van de studie: Diagnostiek	TI ("conservative interventions" OR "habit training" OR "habit retraining" OR "timed voiding" OR "prompted voiding" OR "appliances" OR "continence promotion" OR "toileting" OR "toilet training" OR "physical therapy" OR "continence advice" OR "functional incidental training" OR "urge response" OR "pelvic floor muscle" OR "Biofeedback" OR "treatment" OR medication* OR "drug treatment" OR “drug therapies” OR “drug therapy”) OR AB ("conservative interventions" OR "habit training" OR "habit retraining" OR "timed voiding" OR "prompted voiding" OR "appliances" OR "continence promotion" OR "toileting" OR "toilet training" OR "physical therapy" OR "continence advice" OR "functional incidental training" OR "urge response" OR "pelvic floor muscle" OR "Biofeedback" OR "treatment" OR medication* OR "drug treatment" OR “drug therapies” OR “drug therapy”) OR MH ("Behavior Therapy" OR "Cognitive training" OR "Toilet Training" OR "Life Style" OR "Patient Education as Topic" OR "Fluid Therapy" OR "Pelvic Floor" OR Therapeutics OR "pharmaceutical preparations" OR "Drug Therapy")
#4: Publicatietype	TI ("Systematic review" OR "meta-analysis" OR "meta-analyses" OR "meta analysis" OR "meta analyses" OR "metaanalysis" OR "metaanalyses" OR "randomized" OR "randomised" OR "RCT" OR "controlled" OR placebo* OR "trial" OR "intervention" OR "crossover" OR "cross-over" OR "double-blind" OR "doubleblind" OR "single-blind" OR "singleblind" OR cohort* OR "prospective" OR "longitudinal" OR "observational" OR "follow-up" OR "followup" OR "effectiveness" OR "safety" OR “clinical review” OR “literature review”) OR AB ("Systematic review" OR "meta-analysis" OR "meta-analyses" OR "meta analysis" OR "meta analyses" OR "metaanalysis" OR "metaanalyses" OR "randomized" OR "randomised" OR "RCT" OR "controlled" OR placebo* OR "trial" OR "intervention" OR "crossover" OR "cross-over" OR "double-blind" OR "doubleblind" OR "single-blind" OR "singleblind" OR cohort* OR "prospective" OR "longitudinal" OR "observational" OR "follow-up" OR "followup" OR "effectiveness" OR "safety" OR “clinical review” OR “literature review”) OR MH ("Cross-Over Studies" OR "Double-Blind Method" OR "Prospective Studies" OR "Follow-up Studies" OR "Cohort Studies") OR PT ("Systematic review" OR "meta-analysis" OR "randomized controlled trial" OR "controlled clinical trial")
Limits	Gepubliceerd vanaf 2008
#1 AND #2 AND #3 AND #4 + limits	

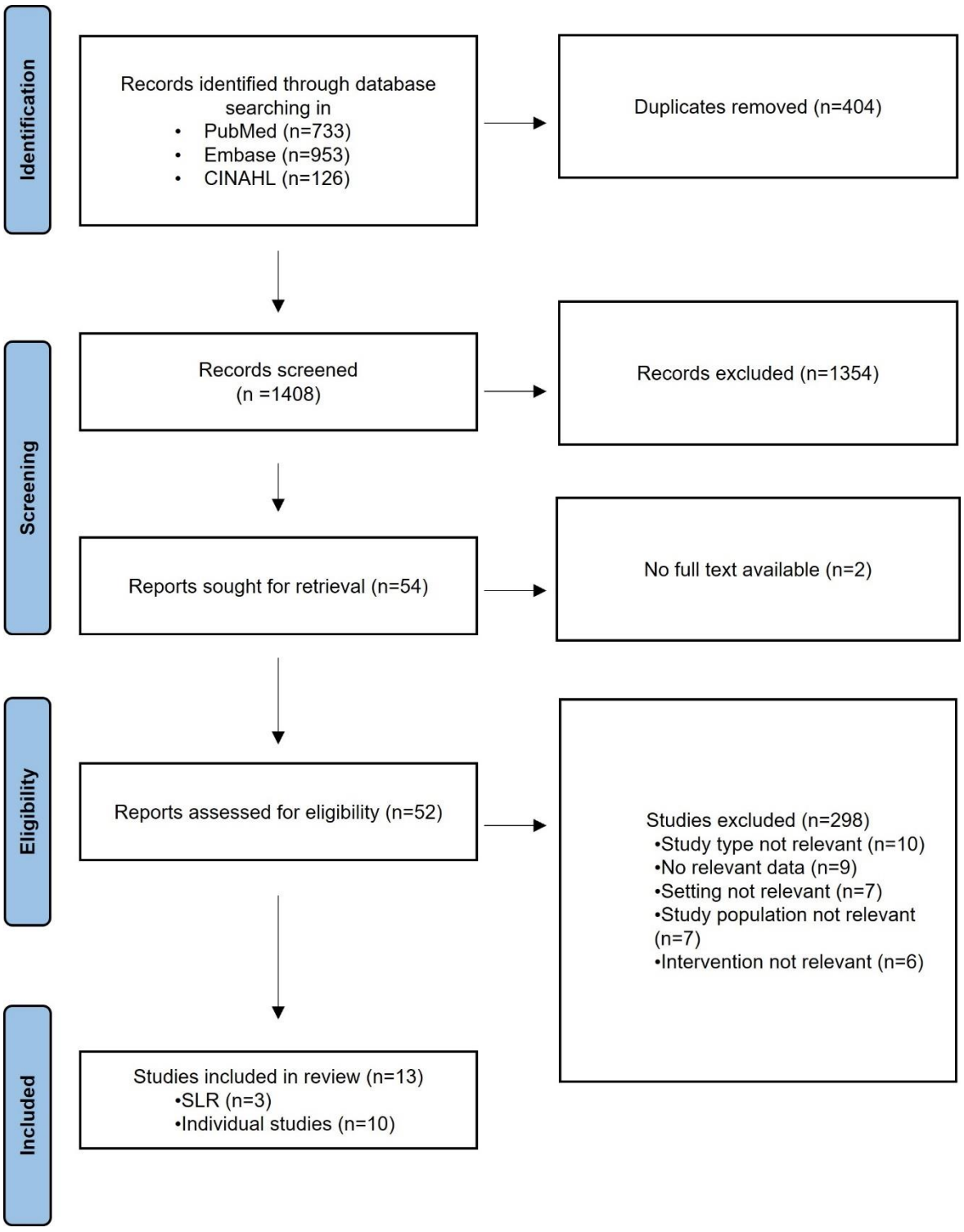
Voor de selectie van relevante artikelen zijn in- en exclusiecriteria geformuleerd. De volgende in- en exclusiecriteria zijn vastgesteld:

Tabel 41. In- en exclusiecriteria.

	Inclusie	Exclusie
Publicatieperiode	/	/
Scope	Wereldwijd	/
Taal	Engels, Nederlands	Overige talen
Studiepopulatie	Ouderen, Gemiddelde leeftijd in onderzoekspopulatie ≥60 jaar	- Zwangere vrouwen - Vrouwen tijdens en voor de menopauze - Kinderen, adolescenten - Dierstudies - Mensen die al langer incontinentie zijn door een degeneratieve ziekte (MS, ALS) - Mensen met een verstandelijke beperking
	Verpleegkundigen en verzorgenden werkzaam in de wijk	Professionals niet werkzaam in de wijk
Focus van de studie	Behandelinterventies: - Bekkenbodemspiertraining - Medicamenteuze behandeling - Advies over leefstijl (o.a. overgewicht, vochtinname) - Toiletgang na attenderen - Verbeteren gewoonte toiletgang - Vaste toiletrondes	- Chirurgische ingrepen - Preventie - Diagnostiek - Interventie niet toepasbaar in de wijk
Studie uitkomsten	- Ervaren kwaliteit van leven door de zorgvrager ((fecal incontinence quality of life questionnaire) - Ervaren gezondheid door de zorgvrager - Ervaren hinder door de zorgvrager als gevolg van urine-continentieproblemen - Ervaren verbetering door de zorgvrager - Symptoomscores (incontinence impact questionnaire; urogential distress inventory) - Grootte van de zorgvraag	
Publicatietype	Peer-reviewed artikelen	- Boek - Letter to the editor - Commentaar - Editorial - Congres abstract
Studiedesign	- Gerandomiseerde gecontroleerde studies (RCT) - Observationele studies - Literatuur review - Meta-analyse	- Case report - Case series - Narratieve reviews

Selectie van artikelen: De selectie van titels/abstracts werd 20% dubbel uitgevoerd met behulp van de software van Rayyan. Verdere selectie van de volledige tekst werd door één onderzoeker volledig gedaan, een andere onderzoeker controleerde de geëxcludeerde artikelen. Twijfelgevallen werden samen besproken tot een consensus was bereikt. Als de inclusiecriteria niet goed toepasbaar waren, werd het artikel voorgelegd aan de werkgroep. De uitkomsten van de selectie van de volledige tekst werden in Excel geregistreerd. Voor de geëxcludeerde artikelen werd de reden van exclusie gegeven. De lijst met geëxcludeerde artikelen werd voorgelegd aan de werkgroep ter controle.

In de afbeelding hieronder wordt de selectie van de literatuur schematisch weergegeven. Uiteindelijk zijn er 13 studies geïncludeerd (3 systematische reviews, 6 RCT's en vier quasi-experimentele studies) die (deels) antwoord geven op de uitkomstvragen. Tabel 42 geeft de details van de geëxcludeerde studies weer.



Figuur 7. Flow-chart van de SLR uitgangsvraag 4.

Tabel 42. Geëxcludeerde artikelen.

Reden voor exclusie	Volledige referentie
Interventie niet relevant (n=6)	Abbas, M. A., Tam, M. S., & Chun, L. J. (2012). Radiofrequency treatment for fecal incontinence: is it effective long-term? *Dis Colon Rectum*, *55*(5), 605-610. https://doi.org/10.1097/DCR.0b013e3182415406
	Bartlett, L., Sloots, K., Nowak, M., & Ho, Y. H. (2011). Biofeedback for fecal incontinence: a randomized study comparing exercise regimens. *Dis Colon Rectum*, *54*(7), 846-856. https://doi.org/10.1007/DCR.0b013e3182148fef
	Bartlett, L. M., Sloots, K., Nowak, M., & Ho, Y. H. (2011). Biofeedback therapy for faecal incontinence: a rural and regional perspective. *Rural Remote Health*, *11*(2), 1630.
	Boselli, A. S., Pinna, F., Cecchini, S., Costi, R., Marchesi, F., Violi, V., Sarli, L., & Roncoroni, L. (2010). Biofeedback therapy plus anal electrostimulation for fecal incontinence: prognostic factors and effects on anorectal physiology. *World J Surg*, *34*(4), 815-821. https://doi.org/10.1007/s00268-010-0392-9
	Leite, F. R., Lima, M. J., & Lacerda-Filho, A. (2013). Early functional results of biofeedback and its impact on quality of life of patients with anal incontinence. *Arq Gastroenterol*, *50*(3), 163-169. https://doi.org/10.1590/s0004-28032013000200029
	Murad-Regadas, S. M., Regadas, F. S. P., Regadas Filho, F. S. P., De Mendonça Filho, J. J., Andrade Filho, R. S., & Da Silva Vilarinho, A. (2019). Predictors of unsuccessful of treatment for fecal incontinence biofeedback for fecal incontinence in female [Article]. *Arquivos de Gastroenterologia*, *56*(1), 61-65. https://doi.org/10.1590/s0004-2803.201900000-17
Geen relevante data (n=9)	Bartlett, L. M., Sloots, K. L., Nowak, M. J., & Ho, Y.-H. (2012). Impact of relaxation breathing on the internal anal sphincter in patients with faecal incontinence. *Australian & New Zealand Continence Journal*, *18*(2), 38-45.
	Bliss, D. Z., Gurvich, O. V., Patel, S., Meyer, I., & Richter, H. E. (2020). Self-management of accidental bowel leakage and interest in a supportive m-Health app among women. *Int Urogynecol J*, *31*(6), 1133-1140. https://doi.org/10.1007/s00192-019-04192-5
	Collins, B., & Norton, C. (2013). Managing passive incontinence and incomplete evacuation. *British Journal of Nursing*, *22*(10), 575-579. https://search.ebscohost.com/login.aspx?direct=true&db=cin20&AN=104181107&site=ehost-live
	Flanagan, L., Roe, B., Jack, B., Barrett, J., Chung, A., Shaw, C., & Williams, K. S. (2012). Systematic review of care intervention studies for the management of incontinence and promotion of continence in older people in care homes with urinary incontinence as the primary focus (1966-2010). *Geriatr Gerontol Int*, *12*(4), 600-611. https://doi.org/10.1111/j.1447-0594.2012.00875.x
	Flanagan, L., Roe, B., Jack, B., Shaw, C., Williams, K. S., Chung, A., & Barrett, J. (2014). Factors with the management of incontinence and promotion of continence in older people in care homes. *J Adv Nurs*, *70*(3), 476-496. https://doi.org/10.1111/jan.12220
	Hägglund, D. (2010). A systematic literature review of incontinence care for persons with dementia: the research evidence. *J Clin Nurs*, *19*(3-4), 303-312. https://doi.org/10.1111/j.1365-2702.2009.02958.x
	Hodgkinson, B., Tuckett, A., Hegney, D., Paterson, J., & Kralik, D. (2010). Effectiveness of educational interventions to raise men's awareness of bladder and bowel health. *JBI Libr Syst Rev*, *8*(30), 1202-1241. https://doi.org/10.11124/01938924-201008300-00001
	Norton, C., Whitehead, W. E., Bliss, D. Z., Harari, D., & Lang, J. (2010). Management of fecal incontinence in adults. *Neurourol Urodyn*, *29*(1), 199-206. https://doi.org/10.1002/nau.20803

Reden voor exclusie	Volledige referentie
	Wijk, H., Corazzini, K., Kjellberg, I. L., Kinnander, A., Alexiou, E., & Swedberg, K. (2018). Person-Centered Incontinence Care in Residential Care Facilities for Older Adults With Cognitive Decline: Feasibility and Preliminary Effects on Quality of Life and Quality of Care [Article]. *Journal of gerontological nursing*, *44*(11), 10-19. https://doi.org/10.3928/00989134-20181010-04
Setting niet relevant (n=7)	Amatya, B., Elmalik, A., Lowe, M., & Khan, F. (2016). Evaluation of the structured bowel management program in inpatient rehabilitation: a prospective study. *Disabil Rehabil*, *38*(6), 544-551. https://doi.org/10.3109/09638288.2015.1047970
	Bliss, D. Z., Westra, B. L., Savik, K., & Hou, Y. (2013). Effectiveness of wound, ostomy and continence-certified nurses on individual patient outcomes in home health care. *J Wound Ostomy Continence Nurs*, *40*(2), 135-142. https://doi.org/10.1097/WON.0b013e3182850831
	Henderson, A., Kamil, I., Meskin, F., Nisar, P., Thomas, G., Bearn, P., & Trivedi, P. (2022). Transanal irrigation in the treatment of functional bowel disorders: a district general hospital perspective. *Gastrointestinal Nursing*, *20*(1), 19-24. https://doi.org/10.12968/gasn.2022.20.1.19
	Sammon, M. A., Montague, M., Frame, F., Guzman, D., Bena, J. F., Palascak, A., & Albert, N. M. (2015). Randomized controlled study of the effects of 2 fecal management systems on incidence of anal erosion [Article]. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society*, *42*(3), 279-286. https://doi.org/10.1097/WON.0000000000000128
	Schnelle, J. F., Leung, F. W., Rao, S. S. C., Beuscher, L., Keeler, E., Clift, J. W., & Simmons, S. (2010). A controlled trial of an intervention to improve urinary and fecal incontinence and constipation [Article]. *Journal of the American Geriatrics Society*, *58*(8), 1504-1511. https://doi.org/10.1111/j.1532-5415.2010.02978.x
	Schnelle, J. F., Simmons, S. F., Beuscher, L., Peterson, E. N., Habermann, R., & Leung, F. (2009). Prevalence of constipation symptoms in fecally incontinent nursing home residents. *J Am Geriatr Soc*, *57*(4), 647-652. https://doi.org/10.1111/j.1532-5415.2009.02215.x
	Whiteley, I., Sinclair, G., Lyons, A. M., & Riccardi, R. (2014). A retrospective review of outcomes using a fecal management system in acute care patients. *Ostomy Wound Manage*, *60*(12), 37-43.
Studie populatie niet relevant (n=7)	Bildstein, C., Melchior, C., Gourcerol, G., Boueyre, E., Bridoux, V., Vérin, E., & Leroi, A. M. (2017). Predictive factors for compliance with transanal irrigation for the treatment of defecation disorders. *World J Gastroenterol*, *23*(11), 2029-2036. https://doi.org/10.3748/wjg.v23.i11.2029
	Boman, E., Nylander, M., Oja, J., & Olofsson, B. (2022). Transanal Irrigation for People With Neurogenic Bowel Dysfunction: An Integrative Literature Review. *Gastroenterol Nurs*, *45*(4), 211-230. https://doi.org/10.1097/sga.0000000000000645
	Collins, E., Hibberts, F., Lyons, M., Williams, A. B., & Schizas, A. M. (2014). Outcomes in non-surgical management for bowel dysfunction. *Br J Nurs*, *23*(14), 776-780. https://doi.org/10.12968/bjon.2014.23.14.776
	Ibrahim, I. K., Hameed, M. M. A., Taher, E. M., Shaheen, E. M., & Elsawy, M. S. A. G. (2015). Efficacy of biofeedback-assisted pelvic floor muscle training in females with pelvic floor dysfunction [Article]. *Alexandria Journal of Medicine*, *51*(2), 137-142. https://doi.org/10.1016/j.ajme.2014.06.001
	Juul, T., & Christensen, P. (2017). Prospective evaluation of transanal irrigation for fecal incontinence and constipation. *Tech Coloproctol*, *21*(5), 363-371. https://doi.org/10.1007/s10151-017-1635-7
	Leo, C. A., Thomas, G. P., Hodgkinson, J. D., Segal, J. P., Maeda, Y., Murphy, J., & Vaizey, C. J. (2019). The Renew® anal insert for passive faecal incontinence: a retrospective audit

Reden voor exclusie	Volledige referentie
	of our use of a novel device. *Colorectal Dis*, *21*(6), 684-688. https://doi.org/10.1111/codi.14587
	Starr, J. A., Drobnis, E. Z., Lenger, S., Parrot, J., Barrier, B., & Foster, R. (2013). Outcomes of a comprehensive nonsurgical approach to pelvic floor rehabilitation for urinary symptoms, defecatory dysfunction, and pelvic pain. *Female Pelvic Med Reconstr Surg*, *19*(5), 260-265. https://doi.org/10.1097/SPV.0b013e31829cbb9b
Type studie niet relevant (n=10)	Davis, K. (2012). Research focus. *Primary Health Care*, *22*(4), 14-14. https://doi.org/10.7748/phc.22.1.14.s13
	Deb, B., Prichard, D. O., & Bharucha, A. E. (2020). Constipation and Fecal Incontinence in the Elderly. *Curr Gastroenterol Rep*, *22*(11), 54. https://doi.org/10.1007/s11894-020-00791-1
	Henderson, M., Tinkler, L., & Yiannakou, Y. (2018). Transanal irrigation as a treatment for bowel dysfunction. *Gastrointestinal Nursing*, *16*(4), 26-34. https://doi.org/10.12968/gasn.2018.16.4.26
	Lee, C., & Lee, J. L. (2022). Is It a Refractory Disease?- Fecal Incontinence; beyond Medication [Article]. *EWHA Medical Journal*, *45*(4). https://doi.org/10.12771/emj.2022.e9
	Meyer, I., & Kissane, L. (2017). Epidemiology, Pathophysiology and Management of Fecal Incontinence in the Older Woman [Review]. *Current Geriatrics Reports*, *6*(2), 64-73. https://doi.org/10.1007/s13670-017-0201-5
	Niu, S., Griebling, T. L., & Kowalik, C. G. (2020). Impact of Frailty on the Treatment of Pelvic Floor Disorders [Review]. *Current Bladder Dysfunction Reports*, *15*(3), 121-126. https://doi.org/10.1007/s11884-020-00590-4
	Norton, C. (2008). Fecal incontinence and biofeedback therapy. *Gastroenterol Clin North Am*, *37*(3), 587-604, viii. https://doi.org/10.1016/j.gtc.2008.06.008
	O'Flynn, S. K. (2019). Faecal incontinence: an update on treatment and intervention. *Gastrointestinal Nursing*, *17*, S12-S15. https://doi.org/10.12968/gasn.2019.17.Sup9.S12
	Probst, M., Pages, H., Riemann, J. F., Eickhoff, A., Raulf, F., & Kolbert, G. (2010). Fecal incontinence: part 4 of a series of articles on incontinence. *Dtsch Arztebl Int*, *107*(34-35), 596-601. https://doi.org/10.3238/arztebl.2010.0596
	Shah, B. J., Chokhavatia, S., & Rose, S. (2012). Fecal incontinence in the elderly: FAQ [Review]. *American Journal of Gastroenterology*, *107*(11), 1635-1646. https://doi.org/10.1038/ajg.2012.284
Artikel niet beschikbaar (n=2)	Lal, N., Simillis, C., Slesser, A., Kontovounisios, C., Rasheed, S., Tekkis, P. P., & Tan, E. (2019). A systematic review of the literature reporting on randomised controlled trials comparing treatments for faecal incontinence in adults. *Acta Chir Belg*, *119*(1), 1-15. https://doi.org/10.1080/00015458.2018.1549392
	Privitera, A. C., Oliveri, C. E., Randazzo, G., Ohazuruike, N. L., Prumeri, S., Politi, A., & Succi, L. (2009). Biofeedback therapy for faecal incontinence: our experience. *Chir Ital*, *61*(2), 149-154.

Kwaliteitsbeoordeling (risk of bias) van de individuele studies

De individuele studies zijn beoordeeld op risk of bias met een tool van de JBI.[27] De keuze van tool is afhankelijk van de studie design (RCT of quasi-experimenteel). De scores (per vraag en overal) per studie zijn weergegeven in Tabel 43 en Tabel 44.

Tabel 43. Risk of bias op basis van de JBI: quasi-experimental design.

Questions according to JBI	Ribas-2018 (pre-post design)	Richter, 2019 (pre-post design)	Lukacz-2015 (pre-post design)	Chew-2011 (pre-post design)
Is it clear in the study what is the 'cause' and what is the 'effect' (i.e., there is no confusion about which variable comes first)?	Yes	Yes	Yes	Yes
Were the participants included in any comparisons similar?	Yes	Yes	Yes	Not Applicable
Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Was there a control group?	No	No	No	No
Were there multiple measurements of the outcome both pre and post the intervention/exposure?	Yes	Yes	Yes	Yes
Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	No	Yes	No	No
Were the outcomes of participants included in any comparisons measured in the same way?	Yes	Yes	Yes	Yes
Were outcomes measured in a reliable way?	Yes	Yes	No	Yes
Was appropriate statistical analysis used?	Unclear	Unclear	Unclear	Yes
Overall appraisal	**Poor**	**Poor**	**Poor**	**Poor**

Note: question 1-8 are from the JBI form; Overall appraisal in the form is Include, Exclude or Seek further info. This is adapted by Pallas into Sufficient, Poor, Exclude.

Tabel 44. Risk of bias op basis van de JBI: RCT's.

	Andy-2020	Bliss-2014	Brown-2019	Pinedo-2009	Tjandra-2008	Barlett-2015
1. Was true randomization used for assignment of	Yes	Yes	Yes	Yes	Yes	Yes

[27] https://jbi.global/critical-appraisal-tools

participants to treatment groups?						
2. Was allocation to treatment groups concealed?	Yes	Yes	Yes	Yes	Unclear	Yes
3. Were treatment groups similar at the baseline?	Yes	Yes	Yes	Yes	Yes	Unclear
4. Were participants blind to treatment assignment?	Yes	Yes	No	Yes	No	No
5. Were those delivering treatment blind to treatment assignment?	Unclear	Yes	No	Yes	No	No
6. Were outcomes assessors blind to treatment assignment?	Unclear	Yes	No	Yes	No	No
7. Were treatment groups treated identically other than the intervention of interest?	Yes	Yes	Unclear	Yes	Unclear	No
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	Yes	Yes	Unclear	Yes	Unclear	Unclear
9. Were participants analyzed in the groups to which they were randomized?	Yes	Yes	Unclear	Yes	Yes	Yes
10. Were outcomes measured in the same way for treatment groups?	Yes	Yes	Unclear	Yes	Yes	Yes
11. Were outcomes measured in a reliable way?	Unclear	Yes	Yes	Yes	Yes	Yes
12. Was appropriate statistical analysis used?	No	Yes	Yes	Yes	Yes	Yes
13.Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	Yes	Unclear	No	Yes	Yes	Yes
Overall appraisal	**Poor**	**Sufficient**	**Poor**	**Poor**	**Poor**	**Poor**

Note: question 1 -13 are from the JBI form; Overall appraisal in the form is Include, Exclude or Seek further info. This is adapted by Pallas into Sufficient, Poor, Exclude

Beoordeling van de kracht van het wetenschappelijk bewijs

Op basis van de literatuur kunnen geen eenduidige conclusies getrokken worden door middel van GRADE. Geen enkele studie onderzocht dezelfde interventie in combinatie met dezelfde uitkomstmaten. Daarnaast was de kwaliteit van de individuele studies allemaal (zeer) laag (met uitzondering van één studie) op basis van de beoordeling van risk of bias van systematische literatuurreviews (SLRs) en individuele studies. De kracht van bewijs is daarom bepaald op basis de

beoordeling van de individuele studies. Individuele studies werden systematisch beoordeeld, op basis van op voorhand opgestelde methodologische kwaliteitscriteria, om zo het risico op vertekende studieresultaten (risk of bias) te kunnen inschatten. Deze beoordelingen zijn te vinden in de Risk of Bias (RoB) tabellen. De gebruikte RoB instrumenten zijn gevalideerde instrumenten die worden aanbevolen door de Cochrane Collaboration: AMSTAR – voor systematische reviews; JBI-RCTs-Quasi-experimentele studies.

Commentaarfase en aanpassingen

Naar aanleiding van de commentaarfase zijn de volgende punten aangepast:

- Enkele tekstuele wijzigingen zijn gemaakt in de aanbevelingen en de moduletekst ten behoeve van de leesbaarheid.
- Bij de aanbeveling over copingstrategieën zijn de voorbeelden van de Incoclub en PVVN uit de aanbeveling gehaald en worden alleen genoemd in de overwegingen.
- De aanbevelingen over vragenlijsten zijn uitgebreid met een kleine tabel met het doel van elke vragenlijst

Evidence tabellen

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Andy, 2020(Andy, Jelovsek et al. 2020) USA Secondary analyses of RCT	To compare the changes in constipation symptoms in women randomized to treatment for FI with education only, loperamide, anal muscle exercises with biofeedback or both loperamide and biofeedback. To compare changes in constipation symptoms among women who reported improved FI symptoms and those who did not report improvement in FI symptoms following treatment.	*Study population* Women with bothersome FI occurring at least monthly over the preceding 3 months (100%, age range: 27.5-93.4 year) N= NR *Setting* 8 sites (not further specified) *Type of incontinence* Bothersome FI: at least monthly fecal incontinence and normal stool consistency	*Inclusion criteria* Women with bothersome FI occurring at least monthly over the preceding 3 months *Exclusion criteria* Women who reported type 1 (hard) or type 7 (watery) stool consistency over the last 3 months using the Bristol Stool Form	*Intervention* (1) Oral placebo plus education only: education consisting of the publicly available pamphlet from the National Institute of Diabetes and Digestive and Kidney Diseases with the deletion of a single reference to the drug loperamide. The pamphlet discusses symptoms, causes, diagnosis, and treatments including dietary treatment for bowel control problems (2) Oral loperamide plus education only: 2 mg of oral loperamide (1 capsule) per day with the option of dose escalation up to a maximum of 4 capsules daily and the option of dose reduction because of adverse effects to 1 capsule every other day + see (1) (3) Oral placebo plus anal sphincter exercise training using manometry-assisted biofeedback: an individualized program that included diagnostic anorectal manometry evaluation, biofeedback strength training, and sensory or urge resistance training (mcompass; Medspira, Minneapolis,MN).	*Patient Assessment of Constipation Symptoms (PAC-SYM) global score*; *PAC-SYM subscale scores* (stool characteristics/symptoms (hardness of stool, size of stool, straining, inability to pass stool), rectal symptoms (burning, pain, bleeding, incomplete bowel movement), and abdominal symptoms (discomfort, pain, bloating, cramps). Subscales and global scores range from 0 (no symptoms) to 4 (maximum score), with decreasing scores representing improvement in defecatory symptoms) A responder to treatment was defined as any subject who showed the minimally important clinical difference, at least a 5-point decrease, in the St Mark's (Vaizey) score at 24 weeks	24 weeks

				(4) Oral loperamide plus anal sphincter exercise training using manometry-assisted biofeedback: See (3).		

Results	Conclusion and Remarks
Placebo + education vs. Loperamide + education *Change in PAC-SYM global score:* Mean change: -0.4 (95% CI: -0.7- -0.2) vs. -0.3 (95% CI: -0.4- -0.2) p-value: 0.819. No significant improvement *Change in PAC-SYM abdominal score:* Mean change: -0.3 (95% CI: -0.5- -0.1) vs. -0.3 (95% CI: -0.5- -0.2) p-value: 0.677. No significant improvement *Change in PAC-SYM rectal score:* Mean change: -0.2 (95% CI: -0.4- 0.0) vs. -0.3 (95% CI: -0.5- -0.2) p-value: 0.379. No significant improvement *Change in PAC-SYM stool score:* Mean change: -0.3 (95% CI: -0.5- -0.1) vs. -0.3 (95% CI: -0.5- -0.2) p-value: 0.537. No significant improvement **Placebo + education vs. placebo + biofeedback** *Change in PAC-SYM global score:* Mean change: -0.3 (95% CI: -0.5- -0.1) vs. -0.1 (95% CI: -0.3-0.0) p-value: 0.169. No significant improvement *Change in PAC-SYM abdominal score:* Mean change: -0.3 (95% CI: -0.5- -0.1) vs. -0.1 (95% CI: -0.3-0.0) p-value: 0.125. No significant improvement *Change in PAC-SYM rectal score:* Mean change: -0.2 (95% CI: -0.4- 0.0) vs. -0.2 (95% CI: -0.3-0.0) p-value: 0.878. No significant improvement *Change in PAC-SYM stool score:* Mean change: -0.4 (95% CI: -0.7- -0.2) vs. -0.1 (95% CI: -0.3-0.0) p-value: 0.169. No significant improvement	*Conclusion* Change in constipation symptoms following treatment of fecal incontinence in women are small and are not significantly different between groups. Loperamide treatment for fecal incontinence does not worsen constipation symptoms among women with normal consistency stool. Women with clinically significant improvement in fecal incontinence symptoms report greater improvement in constipation symptoms. *Remarks* - Enrolled participants underwent a single randomization using a 0.5:1:1:1 allocation to 1 of 4 treatment combinations - Participants and all study staff other than the research pharmacist were masked to the medication assignment. - Limitations mentioned by the author: The concept of MID, the smallest difference in score associated with a clinically meaningful improvement, is frequently used in clinical trials to determine whether the difference observed is not only statistically significant but also clinically relevant. The proposed MID of 0.6 for the PAC-SYM was derived from trials evaluating the treatment efficacy of a medication for chronic constipation. Therefore, the improvement in defecatory symptoms observed in the current study may not have the same magnitude of change in symptoms compared with the clinical trials evaluating the treatment of constipation. - Country was based on authors affiliations *Results of quality check:* Poor

Loperamide + biofeedback vs loperamide + education *Change in PAC-SYM global score:* Mean change: -0.3 (95% CI: -0.5- -0.1) vs. -0.2 (95% CI: -0.3- 0.0) p-value: 0.257. No significant improvement *Change in PAC-SYM abdominal score:* Mean change: -0.4 (95% CI: -0.5- -0.1) vs. -0.1 (95% CI: -0.2- 0.0) p-value: 0.010. Significant improvement *Change in PAC-SYM rectal score:* Mean change: -0.2 (95% CI: -0.4- 0.0) vs. -0.2 (95% CI: -0.3- 0.0) p-value: 0.549. No significant improvement *Change in PAC-SYM stool score:* Mean change: -0.3 (95% CI: -0.4- -0.2) vs. -0.1 (95% CI: -0.3- -0.0) p-value: 0.147. No significant improvement	
Loperamide + biofeedback vs placebo + biofeedback *Change in PAC-SYM global score:* Mean change: -0.3 (95% CI: -0.5- -0.1) vs. -0.3 (95% CI: -0.4- -0.2) p-value: 0.600. No significant improvement *Change in PAC-SYM abdominal score:* Mean change: -0.4 (95% CI: -0.5- -0.1) vs. -0.3 (95% CI: -0.5- -0.2) p-value: 0.862. No significant improvement *Change in PAC-SYM rectal score:* Mean change: -0.2 (95% CI: -0.4- 0.0) vs. -0.3 (95% CI: -0.4- -0.1) p-value: 0.499. No significant improvement *Change in PAC-SYM stool score:* Mean change: -0.3 (95% CI: -0.4- -0.2) vs. -0.3 (95% CI: -0.5- -0.02 p-value: 0.616. No significant improvement	

CI: confidence interval; FI: fecal incontinence; PAC-SYM: Patient Assessment of Constipation Symptoms; RCT: randomised controlled trial

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Bartlett, 2015(Bartlett, Sloots et al. 2015) Australia RCT	To assess whether supplementary home use of a Peritron perineometer with an anal sensor was acceptable to patients and resulted in better outcomes (FI and QOL) compared with standard biofeedback	*Study population* Patients with FI who had not responded to conservative treatment (84%; mean: 61.3 years) N=75 (I: 39; C: 36)	*Inclusion criteria* - 18-80 years	*Intervention* Biofeedback + daily use of a peritron perineometer	*FI grading scale* *Quality of life:* FIQL *(including subscales)* *Incontinent episodes* *Bowel control rating* *Anorectal manometry:* mean resting pressure; maximum squeeze pressure; volume of initial rectal sensation; volume at first urge; maximum tolerable volume. *Patient satisfaction* *Adverse events*	NR (after 43 days from baseline and 35 days after randomization, with a total of 4 weeks home practice completed)
		Setting Townsville Hospital Anorectal Clinic	*Exclusion criteria* - Pregnancy - Gastrointestinal stoma - Terminal or mental illness	*Control* Biofeedback		
		Type of incontinence Not specified				
Results				Conclusion and Remarks		

Biofeedback + peritrion perineometer vs. biofeedback only *FI grading scale*: There was a trend toward greater improvement incontinence compared to the control group (NS) *Quality of life*: there was a trend toward greater improvement. However, this improvement was only statistically significant for the lifestyle (P=0.026) and embarrassment (P=0.026) *Anorectal manometry:* there was a trend toward greater improvement in squeeze pressures for the perineometer group. *Patient satisfaction*: Participants were highly satisfied with the results of treatment (perineometer 9.1/10, control 8.3/10); there were no significant differences between the study arms. *Adverse events*: see article	*Conclusion* Home biofeedback was acceptable and well tolerated by all users. Younger participants significantly benefited from using this technology *Remarks* - Randomisation was unrestricted, computer-generated sequence in opaque envelopes - No blinding was possible - See article for detailed information about the procedure - Intention to treat data - See article for stratified results by age group and gender *Results of quality check:* Poor

FI: Fecal Incontinence; RCT: Randomized controlled trial; QoL: Quality of Life

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Bliss, 2014(Bliss, Savik et al. 2014) USA	To compare the effects of three dietary fiber supplements with differing levels of fermentability to a placebo in community-living	*Study population* Adults with FI N= 206 (53 CMC; 50 GA; 54 Psyllium; 49 placebo) (age; gender NR)	*Inclusion criteria* - At least 18 years old - Living in the community - having FI of loose or liquid consistency at	*Intervention* Dietary fiber: 1) carboxymethylcellulose (CMC) 2) Gum arabic (GA) 3) Psyllium	- *FI frequency*: Subjects recorded in a diary the date and time of every FI episode on each of the 14 days of the baseline period and of the steady amount period 2. A FI episode was a diary report of “incontinent,” which	NR

RCT	individuals incontinent of loose/liquid feces.		least twice in a 2-week period - toileting independently, - Ability to read and write English		was defined for the subjects as the involuntary or accidental leakage of feces from the rectum. FI frequency was measured as the number of FI episodes/day - *consistency of incontinent feces:* subjects used a 4-level classification (hard and formed, soft but formed, loose and unformed, and liquid) - *Amount of FI:* had six levels (none, leakage between buttocks, on an incontinence absorbent product, on underwear, on outerwear, or on shoes/the floor) and again was averaged over each day. - *Overall FI severity:* was calculated as (number of FI episodes/day)X(consistency of the FI episodes/day)X(amount of the FI episodes/day) for each day of the baseline period and steady dose period 2. - *Supplement intolerance* - *Quality of life*: FIQL	
		Setting Home setting	*Exclusion criteria* - Difficulty swallowing - GI tract altered by surgery - Malabsorption disorder - inflammatory bowel disease - GI cancer in active treatment - Allergy to the fibers - Regularly used a laxative or enema - Tube-fed - Unwilling to discontinue taking periodic self-prescribed fiber supplements or anti-diarrheal medications - Score of ≤24 on the Mini Mental State Examination	*Control* Placebo		
		Type of incontinence FI: loose or liquid consistency at least twice in a 2-week period				
Results				Conclusion and Remarks		

Psyllium vs. Placebo *Frequency of FI/day:* Significantly decreased (β-0.27 (se: 0.13); p-value: 0.048): The psyllium group had the greatest percent change in FI frequency, a decrease of 51%, compared to the other groups. FI frequency decreased 20% in the GA group and 11% in the placebo group, and it increased 32% in the CMC group. *FI consistency:* No significant difference (β-0.20 (se: 0.24); p-value: 0.52) *FI amount:* No significant difference (β-0.02 (se: 0.10); p-value: 0.99) *FI severity score:* Significant improvement (54%; β-0.89 (se: 0.39); p-value: 0.02) *Supplement intolerance:* see article. *Quality of life:* There were no significant differences in FIQL, including lifestyle, coping, depression, and embarrassment scores, among the groups in the baseline or supplement periods	*Conclusion* Psyllium supplementation may reduce FI frequency in community-living individuals by as much as half. Formation of a gel in feces appears to be a mechanism by which residual psyllium in feces improved FI. Dietary fiber supplements seem fairly well tolerated overall. Because a decrease in FI frequency is an important goal of patients with FI when a complete cure is not possible, psyllium supplementation appears appropriate as part of conservative treatment. *Remarks* - A parallel-groups, placebo-controlled, single-blind randomized clinical trial. - Randomization was accomplished using computer-generated numbers in blocks of eight concealed in sequentially numbered opaque envelopes created and monitored by the statistician - 14-day run-in baseline period - Persons who regularly performed pelvic floor muscle exercises and/or biofeedback on a maintenance regimen for at least 20 weeks or took a steady dose of anti-motility medication on a regular schedule and still met the FI criteria were also eligible. - Two (4%) withdrew from the placebo group, 6 (11%) from the CMC group, 1 (2%) from the GA group, and 8 (15%) from the psyllium group. Although attrition in the psyllium and CMC supplement groups was more than twice that of the other two groups, the difference was not statistically significant. Reasons for attrition included health problems unrelated to the study (e.g., broken hip), family issues, inability to perform some study procedures, and intolerance of adverse symptoms. (An enrollment flow diagram is available from the corresponding author for up to one year after this publication.) - Data per-protocol analyses are reported in the article - Limitations mentioned by the author: Allowing usual dietary intake likely increased the variability in fecal fiber content but provided a more realistic context, increasing generalizability of findings The composite FI severity score used in this study had not previously been tested *Results of quality check:* Sufficient
CMC vs. Placebo *Frequency of FI/day:* Significantly decreased (β-0.32 (se: 0.13); p-value: 0.020): The psyllium group had the greatest percent change in FI frequency, a decrease of 51%, compared to the other groups. FI frequency decreased 20% in the GA group and 11% in the placebo group, and it increased 32% in the CMC group. *FI consistency:* No significant difference (β 0.13 (se: 0.21); p-value: 0.42) *FI amount:* No significant difference (β-0.09 (se: 0.08); p-value: 0.28) *FI severity score: S*ignificant worsening (44%; β1.50 (se: 0.38); p-value: <0.01)	

Supplement intolerance: see article. *Quality of life:* There were no significant differences in FIQL, including lifestyle, coping, depression, and embarrassment scores, among the groups in the baseline or supplement periods	
GA vs. Placebo *Frequency of FI/day:* No statistical difference (β-0.05 (se: 0.21); p-value: 0.710): The psyllium group had the greatest percent change in FI frequency, a decrease of 51%, compared to the other groups. FI frequency decreased 20% in the GA group and 11% in the placebo group, and it increased 32% in the CMC group. *FI consistency:* No significant difference (β-0.06 (se: 0.21); p-value: 0.76) *FI amount:* No significant difference (β-0.08 (se: 0.09); p-value: 0.43) *FI severity score:* no significant change (β 0.08 (se: 0.39); p-value: 0.84) *Supplement intolerance:* see article. *Quality of life:* There were no significant differences in FIQL, including lifestyle, coping, depression, and embarrassment scores, among the groups in the baseline or supplement periods	

CI: confidence interval; CMC: carboxymethylcellulose; FI: fecal incontinence; GA: gum arabic; GI: gastrointestinal; NR: not reported; RCT: randomised controlled trial; SE: standard error;

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Brown, 2019(Brown, Wise et al. 2020)	To evaluate the effects of Mind Over Matter: Healthy Bowels, Healthy Bladder, a	*Study population* Women with UI or FI (100%, age range: 51-98 year)	*Inclusion criteria* - aged 50 years or older - Lived independently, defined as "living on your own or with someone else, but	*Intervention* Mind Over Matter: Healthy Bowels, Healthy Bladder: combination of education with	*Bowel incontinence severity and quality of life:* St. Mark's Incontinence Score	1 month; 4 months

USA RCT	small-group intervention, on urinary and bowel incontinence symptoms among older women with incontinence.	N= 121 (62 treatment; 59 control)	not needing assistance with daily activities - Could speak and read English; - Had experienced urinary incontinence at least weekly or bowel incontinence at least monthly in the previous 4 weeks	personalized goal setting and action planning to empower women to make and sustain behaviour changes to improve symptoms	A modified Patient Global Impression of Improvement "Check the box that best describes how your accidental bowel leakage is now, compared to how it was 3 months ago"	
		Setting Home setting	*Exclusion criteria* - Acute illness, - Dementia, - Inability to attend all three workshop sessions - Plan to initiate other new treatments for urinary or bowel incontinence during the study time period	*Control* No intervention	Bristol stool scale *Care-seeking* Care-seeking during the study period and intention moving forward were evaluated at 4 months in a questionnaire	
		Type of incontinence Patients with UI or FI (not further specified)				

Results	Conclusion and Remarks
Mind over matter intervention vs. control. *Self-reported improvement of incontinence:* 81% of treated women compared with 27% of women in the control group improved, with 47% compared with 11% reporting that they were very much or much improved (P=<0.05). *St Marks Incontinence Score* Significant improvement in score at 4 months in treatment group compared to control group (p=0.049) *Bristol stool scale* The proportion of participants with desirable type 3 or 4 stool (optimal stool consistency) on the Bristol Stool Form Scale was similar at baseline: 57% (33/58) in the treatment group and 61% (35/57) in the control group (P=.62). At 1 month, 71% (34/48) of the treatment group compared with 41% (18/44) of the control group had type 3 or 4 stools (P=.004) but this difference did not maintain statistical significance at 4 months (72% vs 56%, P=.10) *Care-seeking*	*Conclusion* Participation in a small-group intervention improves symptoms of both urinary and bowel incontinence in older women. Mind Over Matter is a feasible model with potential to bring effective behavioral solutions to the community. *Remarks* - Randomized group treatment trial with a waitlist control group (ratio 1:1) examining the effectiveness of a group intervention - Participants were recruited via flyers, newsletters, newspapers, mailings and e-mailings, and community outreach between May 4, 2017, and June 30, 2017 - Computer generated randomization was performed within each community 1 week before the spring Mind Over Matter workshop and participants were informed of their allocation (spring or fall) at that time. - See articles for a detailed description of the intervention - The majority of participants (n=73, 60%) had both urinary and bowel incontinence; 44 (36%) had isolated urinary incontinence; 1 (1%) had isolated bowel incontinence; data were missing on either urinary or bowel incontinence at baseline for three participants (3%). - Only data from the patients with FI were reported in this data extraction sheet - Not all outcomes were reported for FI only *Results of quality check:* Poor

Between-group differences in rates of care-seeking during the study or in plans to seek care at the end of the study did not differ.	

FI: fecal incontinence; UI: urine incontinence; RCT: randomised controlled trial

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Chew, 2011 (Chew, Sundaraj et al. 2011) Australia Before-after study (quasi-experimental)	To investigate the potential use of S3 TENS in the treatment of idiopathic faecal incontinence.	*Study population* Patients with FI (mean age: 66.6 years; 81.3% women) N=16	*Inclusion criteria* - Men and women aged 20–90 years, - Failed medical therapy: at least 1 month of loperamide use where the patients were dissatisfied with the treatment and considered the medical therapy to have failed - Wexner score ≥10 and ability to comply with questionnaires - Attendance at clinics.	*Intervention* S3 transcutaneous electrical nerve stimulation (TENS) over 2 hours daily	*FI severity:* FISI *QoL:* FIQOL *Number of incontinent episodes:* 7-day bowel diary *Satisfaction of patient:* self-assessment visual analogue scale *Maximum resting and squeeze pressures* *Pudendal nerve terminal motor latencies* *Rectal volume to first sensation, first urge and maximum tolerable volume*	Baseline (before start intervention), after 1 month and after 3 months (during intervention); 2 months after intervention
		Setting Consultation clinic *Type of incontinence* idiopathic faecal incontinence: Wexner score ≥10	*Exclusion criteria* - No full-thickness rectal prolapse on clinical examination or on defaecating proctogram - Noncompliance with the treatment, i.e. unable to follow instructions in the appropriate use of TENS machine or unable to attend the required follow up or complete questionnaires - Unwilling to proceed after recruitment because of personal choice - Acute medical condition that interrupted the use of TENS - Major anal sphincter injury (a few centimetres of sphincter defect) or levator injury detected on ultrasound - Neurological disease, such as multiple sclerosis or spinal cord injury; - Impaired general health that could affect active participation in the trial	*Control* Before the intervention		
Results				Conclusion and Remarks		

After 1/3 months during intervention: *FI severity index:* After 3 months the FISI improved significantly in 69% of the patients. 31% had more than 50% improvement. *QoL:* All components of the FIQOL scale improved after TENS, but of these, only coping／behaviour was statistically significant. *Number of incontinent episodes:* Examination of the 7-day bowel diary showed a reduction in the number of incontinent episodes per week both for incontinence to gas (P = 0.4316) and to solid and／or liquid stool (P = 0.0017). *Satisfaction of patient:* According to the patients' self-assessment visual analogue scale, all claimed to be improved, all giving a score of ≥ 6／10 for satisfaction. Fourteen (87.5%) scored ≥6／10 for bowel control and all scored ≥2 (scale: -5 to +5) for their impression of improvement after the treatment. After intervention: *FI severity index:* At a mean follow up of 19.7 months (range 13.1–27.4), there was continuing and further improvement in the mean FISI. The improvement in FISI between pretreatment and medium-term follow up. was statistically significant. *Satisfaction*: 12 reported no deterioration with no further interventions required. Four had deteriorated and three of these improved after recommencement of TENS. See article for: *Maximum resting and squeeze pressures; Pudendal nerve terminal; motor latencies;* *Rectal volume to first sensation, first urge and maximum tolerable volume*	*Conclusion* S3 TENS seems to be a promising noninvasive method to treat faecal incontinence. However, further study is required. *Remarks* - Consecutive patients - All patients were given a written questionnaire to complete at home. Patients who did not - understand the questionnaire were assisted by the practice nurse by telephone - 50% of the patients were excluded before start intervention - Small number of patients - Patients compliance was not reported *Results of quality check:* Poor

FI: Fecal incontinence; FISI: fecal incontinence severity index; FIQOL: fecal incontinence quality of life scale; QoL: Quality of Life; TENS: transcutaneous electrical nerve stimulation

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Lukacz, 2015(Lukacz, Segall et al. 2015) USA Before-after study) (quasi-experimental study)	To evaluate the efficacy, safety, and tolerability of an anal insert device for the conservative management of fecal incontinence	*Study population* Patients with FI (90%, age range: 33.9-88.9 year) N= 91 (intention to treat; 73 completed the intervention) *Setting* 3 clinical sites *Type of incontinence* FI: FI severity score ≥12, and at least weekly leakage of solid and/or liquid type stool (mixed with passive predominant (33%), mixed with urge predominant (28%), passive only (21%), and urge only (19%))	*Inclusion criteria* - Subjects ≥18 years of age - FI severity score ≥12, and at least weekly leakage of solid and/or liquid type stool *Exclusion criteria* - Individuals with anorectal pathology (≥third degree hemorrhoids, rectal prolapse, anal fissure or stricture, perianal abscess or fistula, anismus, recent rectal surgery, fecal impaction, or clinically significant rectocele) - Need for rectal suppository use - IBD - Immune suppression - spinal cord injury or neurologic disease - Pregnancy/breastfeeding, - Any major medical illnesses	*Intervention* 12 weeks of continuous anal insert device use *Control* NA (before intervention)	*FI frequency*: bowel diaries. *FI severity*: Score based on Cleveland Clinic Fecal Incontinence/Wexner score, modified with e.g. the term “lifestyle alteration” to “quality of life impact” *QoL*: Part of FI severity score (see above) *Overall subject satisfaction:* 5-point Likert scale *Ease of use, usability, and comfort*: 10-point scale *Adverse events* objective success was defined as ≥50% reduction in FI episodes, and subjective success was measured by reduction in FI severity score.	12 weeks
Results				Conclusion and Remarks		

Anal insert device *FI frequency*: 62% (95% CI, 51%–71%; 56/91) demonstrated ≥50% reduction in FI frequency. Median fecal incontinence frequency was reduced by 82% from 0.9 (mean 1.1 ± 0.9) at baseline to 0.2 (mean 0.3 ± 0.4) episodes of leakage per day at 12 weeks ($p < 0.001$). *FI severity score:* Mean fecal incontinence severity scores improved by 32.4% (16.2, ±2.1 vs 10.9, ±4.4 of 20, $p < 0.001$) *Patients' satisfaction/usability:* 78% of the completers were very or extremely satisfied with the device and 91% of them rated the overall experience, comfort, and ease of insertion ≥8 on the 10-point scale (median 9.5) with mean and median experience scores above 8 at each weekly assessment throughout treatment. Eighty percent of the completers reported that they liked the inserts "quite well," "very well," or "extremely well." "Ease of use" and "effectiveness" were the leading reasons why subjects liked the anal insert (60% and 49%) when surveyed in the 12th week of treatment. *Adverse events*: see article	*Conclusion* The anal insert device provides a conservative, safe, and effective management strategy for individuals with fecal incontinence, with high patient satisfaction and low adverse event rates. *Remarks* - No control group - Only intention-to-treat results are shown. - The way of measuring severity score was not validated - Lack of randomisation - No blinded assessment - Low number of men enrolled in this trial limits the generalizability of these results - Results of Quality of life are not reported in the article, while it was reported as outcome measure *Results of quality check:* Poor

FI: fecal incontinence; NA: Not applicable; RCT: randomised controlled trial

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Pinedo-2009(Pinedo, García et al. 2009) Chile RCT	To evaluate the effect of topical oestrogens in controlling symptoms of FI in postmenopausal women.	*Study population* Postmenopausal women (100%, mean: I: 69; C: 66 year) N=35 (intervention: 18; placebo:17) *Setting* Outpatient clinic in the Colorectal Unit at Pontificia Universidad Cato´ lica de Chile *Type of incontinence* FI (not specified)	*Inclusion criteria* - Post menopausal women (at least 1 year) without hormonal substitution - Wexner's FI score > 5 - Anal ultrasound with: < 50% damage to external sphincter - Accepted informed consent *Exclusion criteria* - Perianal lesions - History of endometrial, breast or cervix cancer - Allergy to oestrogens	*Intervention* Topical oestrogens on the mucosa of the anal canal *Control* Placebo on the mucosa of the anal canal	*FI intensity:* Wexner's FI score. difference of 50% was judged successful *Quality of life*: ECIF, a quality-of-life questionnaire validated and accepted for the Spanish language *Adverse events and complications*	6 weeks

Results	Conclusion and Remarks
Topical oestrogen vs Placebo *FI intensity:* both groups (oestrogen and placebo) had statistically significant improvements, with no statistical difference between groups (P = 0.521) *Quality of life:* After treatment there was a minimal improvement, especially regarding embarrassment. This difference was not significant. *Adverse events and complications:* See article	*Conclusion* There is improvement of continence in both groups that had the ointment applied; nonetheless this study could not show that topical oestrogens improves FI more than a placebo does. *Remarks* - Small sample size - Short follow-up - Not reported how randomisation was done - Double blind *Results of quality check:* Poor

FI: fecal incontinence; RCT: randomised controlled trial

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Ribas-2018(Ribas and Muñoz-Duyos 2018) Spain Before-after study (Quasi experimental)	To assess the correlation between the improvement in stool consistency by fiber supplementation and the changes in urgency and number of FI episodes and in the QoL of patients with FI	*Study population* Patients with FI (77%, mean: 65 years) N=61	*Inclusion criteria* - Age > 18 years - One or more episodes per week of FI, defined as the involuntary loss of liquid or solid stool - Fecal urgency (patients with a history of FI episodes, but reporting only defecatory urgency in their bowel diary and referring not to leave home to avoid incontinence episodes) - FI lasting more than 6 months - Bristol scale 5–7 or alternating stools including episodes of Bristol > 4	*Intervention* Dietary advice + methylcellulose (500 mg every 8 hours)	*Number of FI episode*: a reduction of 50% or more in the mean number is defined as successful. *Bowel movements/week*: based on bowel diary *FI severity*: St Mark's Incontinence score *QoL*: Rockwood Fecal Incontinence Quality of Life *Satisfaction:* Bowel satisfaction score (0-10) *Adverse events*	6 weeks
		Setting coloproctology units of two institutions (Consorci Sanitari de Terrassa and Hospital Universitari MútuaTerrassa)	*Exclusion criteria* - Bristol ≤ 4 - Pregnancy - Receiving other treatments for FI such as biofeedback	*Control* NA (before intervention)		
		Type of incontinence FI/Fecal urgency				

Results	Conclusion and Remarks
Dietary advice + methylcellulose *Number of FI (>50% reduction):* 60.6% of the patients after treatment with methylcellulose. *Bowel movements/week:* Significant decrease in bowel movement (p <0.001) *FI severity*: The St Mark's score significantly decreased from a mean of 14–8.6 (p < 0.001). *Bowel satisfaction*: The bowel satisfaction score improved from a mean of 3.1–7 (p < 0.001). *QoL*: QoL questionnaires were complete in 37 cases both before and after treatment. There were overall improvements in the four domains, which were statistically significant in lifestyle and coping/behavior. *Adverse events*: See article	*Conclusion* FI may significantly improve with methylcellulose in selected cases. Assessment of fecal consistency and initial treatment with methylcellulose could be started at primary care level to reduce the need for specialist referral. *Remarks* - No control group - See article for detailed results of the bowel diary - Small sample size - Limitations mentioned by the author: First, the treatment was prescribed but not administered by the team, although all patients confirmed having taken it when they were directly questioned suggests that compliance was good but not guaranteed. Second, dietary advice was provided in conjunction with the bulking agents and could be a confounder. We systematically asked the patients if they had followed the dietary advice, and only 37% of patients made minor changes while the rest followed their usual diet. Nevertheless, a further study could be required comparing the effect of dietary changes vs. methylcellulose. Finally, the dropout rate was higher than expected, although we still included a sufficient number of patients to satisfy the power calculation. - See dietary advice sheet in article *Results of quality check:* Poor

FI: fecal incontinence; QoL: Quality of Life

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Richter, 2019(Richter, Dunivan et al. 2019) USA Before-after study (quasi-experimental study)	To characterize clinical success, impact on quality of life, and durability up to 1 year in women with fecal incontinence (FI) responsive to an initial test period with a trial vaginal bowel control system.	*Study population* Women with FI (100%, mean: 61.3) N=73	*Inclusion criteria* - Women 19 years or older - With a history of FI for at least 6 months and a minimum of 4 FI episodes during the 2-week baseline bowel diary evaluation period - Participants also had to undergo a successful evaluation and treatment with a trial VBC system, which was a similar but less durable version of the long-term system.	*Intervention* Use of a vaginal bowel control system (intravaginal device) for 12 months The system consists of a silicone-coated vaginal insert with posteriorly oriented balloon and detachable pump that reversibly deflects the rectovaginal septum and interrupts the passage of stool.	*Responder to treatment:* proportion of patients with a 50% or greater reduction in the mean number of FI episodes by bowel diary *FI severity:* St Mark's (Vaizey) questionnaire *Patient Global Impression of Improvement* *Quality of Life:* FIQOL *Adverse events*	3 months (primary outcome time-point), 6 months, and 12 months
		Setting Multi-center: clinical sites (n not reported)	*Exclusion criteria* - FI primarily due to chronic watery diarrhea unmanageable by medications or diet - Concurrent medical conditions such as urinary or colorectal infections, presence of a rectovaginal fistula, tumor of genitourinary or colorectal origin, inflammatory bowel disease, chronic pain syndromes of the pelvis and/or anorectal origin, vaginal prolapse extending beyond the plane of the hymen, previous rectal or pelvic surgery within the last 12 months (24	*Control* NA (before intervention)		
		Type of incontinence FI: not specified				

			months in the case of cancer), congenital anorectal malformation - Significant urogenital atrophy, presence of an open wound or tear in the vagina or anus - Pregnancy or subjects planning pregnancy in the next 5 months - Any other significant medical conditions that would interfere with study participation such as psychiatric or neurological disorders or active alcohol or drug abuse that would increase the subject's risks due to participation			

Results	Conclusion and Remarks
Intervaginal device *FI episodes:* At 3 months, the success rate was 73% (95% CI, 61%–82%; n = 53/73; P < 0.0001); after 6 and 12 months: the success rate was 90% (Intention to treat) *FI severity:* Mean incontinence episodes and St Mark's scores significantly decreased from baseline to all time points. *Patient Global Impression of Improvement (PGI-I):* More than 90% of participants reported that their symptoms improved on the PGI-I at 3 months, and this increase was sustained at 12 months (per-protocol) *Quality of Life:* The FIQOL scores significantly improved in all subscales as well (per-protocol) *Adverse events*: see article	*Conclusion* In women with successful fitting and initial treatment response, durable efficacy was seen at 3, 6, and 12 months by objective and subjective measures, with favorable safety. *Remarks* - 54 (74%) of the total population completed the treatment period (12 months) (per-protocol population) - Limitations mentioned by the authors: Another limitation is that the current study population had relatively severe FI, with a minimum of 4 major incontinence episodes over 2 weeks, and therefore, the results may not be generalizable to those with less severe FI or staining only. Because this was a safety and efficacy trial with strict inclusion/exclusion criteria, external validity, or generalizability, may be limited to populations different from the current participants *Results of quality check:* Poor

FI: Fecal incontinence; FIQOL: Fecal Incontinence Quality of Life Scale; QoL: quality of life

Author, year, country, type of study	Study objective	Study population (age; %female) Setting; Type of incontinence	Inclusion and exclusion criteria	Intervention; control	Outcome measures	Time of outcome assessment
Tjandra, 2008(Tjandra, Chan et al. 2008) Australia RCT	To compare the effect of sacral neuromodulation with optimal medical therapy in patients with severe fecal incontinence	*Study population* Patients with severe FI (mean:63 years; 93%) N=60	*Inclusion criteria* - Involuntary passage of solid or liquid stool at least once per week - Refractory to medical therapy and pelvic floor exercises - Aged 35 to 86 years	*Intervention* Sacral nerve stimulation (data outside of scope of this review)	*FI episodes*: 2-week bowel diaries *FI severity*: Wexner's scale *Quality of life:* FIQL, SF-12	3 months and 12 months
		Setting A multidisciplinary pelvic floor clinic.	*Exclusion criteria* - Rectal prolapse - Inflammatory bowel disease - Congenital anorectal malformation - Neurologic disorders - Stoma in situ - Pregnancy - External anal sphincter defect of more than 120° of the circumference - Bleeding diathesis - Mental or physical disability precluding adherence to study protocol	*Control* Optimal medical therapy: bulking agents, pelvic floor exercises with a team of dedicated physiotherapists, and dietary management on fluid and fibers with a team of dieticians. The frequency of attendance varied depending on needs; generally this was at monthly intervals for the first six months and two monthly intervals for the second six months. Each pelvic floor exercise session lasted 20 minutes. Biofeedback was provided with digital guidance. Patients were asked to perform identical sets of 50 contractions twice per day at home. Imodium® was used in 11 patients as a bulking agent to help improve continence		
		Type of incontinence Severe FI: significant fecal incontinence (Wexner's incontinence score > 12)				
Results				Conclusion and Remarks		

FI episodes: No significant change in number of episodes, number of days with incontinence, staining or pads per week, at 3 months or 12 months. *FI severity*: No significant improvement in Wexner's score at 3 months or 12 months. *Quality of life:* No significant improvement in FIQL scores or SF-12 quality of life scale at 3 months or 12 months	*Conclusion* In the control group undergoing optimal medical therapy, there was no significant improvement in fecal continence *Remarks* - The intervention (sacral nerve stimulation) was outside of the scope of this review, therefore data was extracted for the control group only - There was complete compliance with follow-up - Limitations mentioned by authors: The follow-up was only for 12 months. However, some of our control patients who underwent optimal medical therapy have found it difficult to continue with their disability and have sought therapy with SNS after the 12-month study. The lack of a dramatic response with medical therapy was surprising, but this could relate to inclusion of patients with more severe fecal incontinence with a high proportion of patients having pudendal neuropathy. *Results of quality check:* Poor

FI: Fecal Incontinence; FIQL: Fecal Incontinence Quality of Life Scale; RCT: Randomised Controlled Trial; SF-12: Short Form 12; SNS: Sacral Nerve Stimulation

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Hodgkinson-2008(Hodgkinson, Josephs et al. 2008) JBI library of systematic literature reviews SLR	What is the effect of educational interventions directed at healthcare staff, carers or clients on their knowledge of urinary and faecal incontinence in older adults? What is the effect of educational interventions directed at healthcare staff, carers?? or clients on the frequency of incontinent episodes in older adults? What is the effect of educational interventions directed at healthcare? staff/carers/clients on number of hours spent on the management of incontinence?	*Type of incontinence* Clients with FI and/or UI: a participant was defined as incontinent if there was a complaint of any involuntary leakage of urine and/or the involuntary loss of flatus, liquid or solid stool. *Intervention* Education strategies focusing on: • Treatment of transitional causes of incontinence for example urinary tract infection • Constipation, diabetes control, medication modification, pain management, and depression • Fluid control • Toilet technique and correct posture on the toilet • Bladder training • Bowel management	*Inclusion criteria* • Clients with FI; • At least 65 years old; • Clients with carers and healthcare staff who care for them • Systematic reviews of clinical trials, randomised controlled trials, controlled trials, clinical trials • English language *Exclusion criteria* Not specified	*Search strategy* Cochrane, PubMed, CINAHL, EMBASE, Australian Institute of Health and Welfare (AIHW), National Health and Medical Research Council (Aust) (NHMRC), Continence Foundation of Australia (CFA), International Continence Society (ICS), The NHS Centre for Reviews and Dissemination, Netting the Evidence (ScHARR), Database of Abstracts of Reviews of Effectiveness (DARE), Centre for Evidence-based Nursing - based at University of York, Centre for Evidence-Based Medicine (Oxford University), Association for Continence Advice (ACA), World Health Organization (WHO), Agency for Healthcare Quality and Research (AHRQ), Centers for Disease Control and Prevention (CDC), and National Guidelines Clearing House; Articles published between 1990 and 2007; Only key search terms were reported in the article; PRISMA flowchart was presented in the article. *Numbers of included articles* **SLR:** 46 studies (20 RCTs; 3 SLRs; 23 controlled trials) **MA:** NA *Study endpoints*

		• Pelvic floor muscle exercises • Biofeedback • Electrical stimulation • Urethral massage for men • Knowledge of pharmacotherapy e.g. oestrogen, cranberry, anticholinergics, antispasmodics • Knowledge of medication modification • Environmental modification • Containment aids and continence products		○ Increase in client/carer/healthcare staff knowledge of continence/incontinence. ○ Changes in number/frequency of incontinent episodes experienced by the client. ○ Changes in use of continence aids and/or cost of management of incontinence. ○ Changes in number of hours spent on the management of incontinence.
Results			Conclusion and Remarks	

PME with biofeedback (3 studies): Study 1 (male +females) : found significant reductions in number of incontinence episodes per week for all 4 intra-group comparisons but no significant differences between groups. Each treatment group had reductions in the mean number of incontinence episodes per week from 5-6 to <1 to 2 episodes per week. Study 2 (males + females): a significant decrease in the number of faecal incontinence episodes per week from 11.8 ±0.4 to 2.0 ± 0.2 per week (p=0.001). Study 3 (only female): No significant improvement compared to placebo group. Functional incidental training (FIT) (2 studies): combines prompted voiding with endurance exercises (e.g. walking, repeat sit-stand manoeuvre). Study 1 (veterans at a home) found no significant difference in the number of residents incontinent of stool between treatment and control groups. Study 2 (nursing home residents) reported a significant reduction in the number of checks that found incontinence of stool for the FIT group but there was no difference in the control group. Mixed strategies (1 study): Patients with home care received counselling from nurse continence advisor on fluid and caffeine intake reduction, performance of pelvic muscle exercises, possible toileting programs and appropriate continence products. By the end of the program (6 months), 16% became fully continent.	*Conclusion* PME with biofeedback may be beneficial in reducing the incidence of FI in population of males + females, but larger RCT are required for this result to be definitive. Due to the poor statistical power of the only trial available, no conclusion as to the effectiveness of PME with biofeedback in faecally incontinent women >65 years of age can be made. In a nursing home population FIT may be effective in reducing FI, however, conflicting results between trials makes this conclusion less convincing. Mixed strategies for managing FI show some promise. However, the study design precludes any definitive measure of effectiveness for this approach. *Remarks* - Only the results of the change in number/frequency of incontinent episodes are shown in this data extraction sheet - Limited number of articles reporting data about FI - Not all studies were applicable for the home-setting - Limitations mentioned by the authors: the use of self-report bladder and incontinence diaries could be a limitation as to the credibility of the size if not the significance of a reported effect in any given trial. *Results of AMSTAR* - In-exclusion criteria and PICO (yes) - Statement of pre-defined protocol (no) - Comprehensive literature study (yes) - Study selection in duplicate (No) - Data extraction in duplicate (yes) - List of excluded articles (no) - Included studies described in adequate detail (yes) - Risk of bias assessment (yes) - Meta-analyse: NA - Conflict of interest (yes)

CI: confidence interval; FI: fecal incontinence; FIT: Functional incidental training; MA: meta-analysis; Mg: milligram; NA: not applicable; RCT: randomised controlled trail; SLR: systematic literature review; UI: Urine incontinence

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Omar 2013(Omar and Alexander 2013) Cochrane Database of Systematic Reviews Worldwide SLR	To assess the effects of drug therapy for the treatment of faecal incontinence. In particular, to assess the effects of individual drugs relative to placebo or other drugs, and to compare drug therapy with other treatment modalities.	*Type of incontinence* FI: the involuntary loss of solid or liquid faeces, including chronic diarrhoea *Intervention* Drug treatment: • Constipation agents: loperamide, codeine phosphate and co-phenotrope. • Laxatives: lactulose, a galactose-fructose disaccharide • Drugs acting on anal sphincter tone: phenylephrine gel, zinc-aluminium ointment, sodium valproate	*Inclusion criteria* • RCTs; quasi-randomised trials; cross-over trails • People over 18 years old with symptoms of FI • At least one trial group treated with any type of drug (other than suppositories and enemas). • Comparison interventions may include placebo, conservative (physical) treatments, nutritional interventions, surgery, suppositories, enemas and other drugs. *Exclusion criteria* • Trials of suppositories, enemas or fibre supplements	*Search strategy* The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and MEDLINE in process, and handsearching of journals and conference proceedings. Articles published between till 21 June 2012; Full strategy was reported in the article; PRISMA flow-chart was presented in the article; Included also conference abstracts. *Numbers of included articles* **SLR:** 18 articles reporting on 16 studies→ only two studies were relevant **MA:** NA *Study endpoints* **Participant observations** • Number of people failing to achieve complete continence • Number of people failing to improve • Frequency of incontinence (diary or self-report) • Degree of incontinence (e.g. stool weight) • Number of pad changes • Incontinence score • Episodes of faecal urgency **Participant satisfaction** • Self-reported satisfaction with treatment **Clinician observations (anorectal physiological measurements)** • Maximal resting anal canal pressure (pressure or EMG) • Duration of anal canal pressure during voluntary contraction

				• Rectal sensation (by balloon insuflation or electrical stimulation) • Magnitude of fall in resting anal pressure during rectal distension (rectoanal inhibitory reflex) • Saline retention test **Adverse effects** • Constipation, abdominal pain, headache and nausea. **Quality of life (health status measures)** • Condition-specific measures of effect of faecal incontinence on quality of life (for example, Faecal Incontinence Quality of Life Scale,) • Psychological measures (for example, HADS,) • Generic health-related quality of life measures (for example, Short Form 36 Profile) **Socioeconomic measures** • Costs of interventions • Cost-effectivenes of interventions **Other outcome measures:** • Any other outcome measure later judged important by the review authors

Results	Conclusion and Remarks
<u>Osmotic laxatives (lactulose)</u> (2 studies): Lactulose vs. Placebo (1 study): *Participant observations:* elderly people in a geriatric unit receiving lactulose required significantly less help from nurses for their bowel function, and soiled significantly fewer articles of clothing and linen. *Participant satisfaction*: NA *Clinician observations (anorectal physiological: measurements*: NA *Quality of life (health status measures)*: NA *Adverse events:* see article. *Costs and cost-effectiveness:* see article. Lactulose alone vs. Lactulose plus rectal stimulant and weekly enemas (1 study):	*Conclusion* No specific conclusions on the two relevant studies extracted here General conclusion of SLR: The small number of trials identified for this review assessed several different drugs in a variety of patient populations. The focus of most of the included trials was on the treatment of diarrhoea, rather than FI. There is little evidence to guide clinicians in the selection of drug therapies for faecal incontinence. The data available are consistent with the use of anti-diarrhoeal/constipating drugs to improve the symptoms of people suffering from FI due to liquid stools. Larger, well-designed controlled trials, which use the recommendations and principles set out in the CONSORT statement, and include clinically important outcome measures, are required. *Remarks* - SLR included also non-relevant study populations (cancer patients; age <60 years) - Only the relevant studies were extracted in the data extraction sheet - Cochrane SLR *Results of AMSTAR* - In-exclusion criteria and PICO (yes) - Statement of pre-defined protocol (yes) - Comprehensive literature study (yes) - Study selection in duplicate (yes)

Participant observations: in patients with FI and chronic rectal emptying impairments aged 65 years or older in long-term care units, the number of FI episodes and soiled laundry did not differ. between people receiving lactulose and those receiving lactulose along with a rectal stimulant and weekly enemas *Participant satisfaction*: NA *Clinician observations (anorectal physiological: measurements*: NA *Quality of life (health status measures)*: NA *Adverse events:* see article. *Costs and cost-effectiveness:* see article	- Data extraction in duplicate (yes) - List of excluded articles (yes) - Included studies described in adequate detail (yes) - Risk of bias assessment (yes) - Meta-analyse: NA - Conflict of interest (yes)

CI: confidence interval; FI: fecal incontinence; MA: meta-analysis; mg: milligram; NA: not applicable; RCT: randomised controlled trial; SLR: systematic literature review;

Author, year, country, journal, type of study	Study objective	Type of incontinence; Intervention	Inclusion and exclusion criteria	Search strategy, number of included studies, designs of included studies, study endpoints
Riemsma-2017(Riemsma, Hagen et al. 2017) BMC medicine Worldwide SLR	To assess cure rates from treating UI or FI and the number of people who may remain dependent on containment strategies.	*Type of incontinence* FI: Defined as loss of control of liquid or solid stool *Intervention* any intervention in line with the 5th International Consultation on Incontinence (ICI) treatment algorithms (which includes primary, secondary and additional lines of therapy): - Biofeedback; - Sacral nerve stimulation - TENS	*Inclusion criteria* • Any design • Adult patients (≥18 years) with UI or FI • Reporting cure or success rates • Sample size: ≥ 50 patients • Evaluating any intervention in line with the 5th International Consultation on incontinence treatment algorithms (which includes primary, secondary and additional lines of therapy) • A follow-up time ≥ 3 months *Exclusion criteria* • NR	*Search strategy* Medline, Embase, PsycINFO, the Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, and PEDro; Articles published between January 2005 till June 2015; Full strategy was not reported in the article; PRISMA flow-chart was presented in the article; Included also conference abstracts. *Numbers of included articles* **SLR:** 127 articles of 98 studies (not all studies are relevant for our guideline): 11 articles relevant for FI **MA:** NA

		- Methylcellulose (Citrucel) and loperamide (Imodium) - Standard conservative treatment - Biomaterial injection		*Study endpoints* **Efficacy results** - Cure rates (N of studies not reported): no episodes of FI at trial specified time points, of at least 3 months. - Improvements/success rates (N of studies not reported): the percentage of patients with no limitations to activities of daily living, quality of life, or social interaction
Results			Conclusion and Remarks	
FI <u>Biofeedback</u>: *Cure rate (1 study):* 40.8% after 6 months; 35.8% after 3 years; 29.0% after 5 years (only male) <u>Methylcellulose plus loperamide:</u> *Cure rate (1 study):* 46% at 3 months Improvement rates: See article			*Conclusion* Methylcellulose plus loperamide was assessed in one study, with a cure rate of 46% at 3 months. In men, cure rates for biofeedback were 40.8% at 6 months, 35.8% at 3 years and 29% at 5 years' follow-up. *Remarks* - Only cure rates are reported in this data extraction sheet are reported. Some interventions did not report cure rates. Only studies with a median/mean age of 60+ were included in this data extraction sheet - Little information about the included articles - No comparison group - No studies meeting inclusion criteria were found for the following interventions for FI: education of patient and/or caregiver, diet and eating pattern modifications, dietary fiber supplements, bowel habit training, rectal irrigation, continence products such as pads or anal plug for containment, PFMT, sphincteroplasty, artificial bowel sphincter, dynamic graciloplasty, antegrade continence enema, colostomy, magnetic anal sphincter, and puborectal sling. - Not all interventions mentioned in the SLR are relevant for our guideline *Results of AMSTAR* - In-exclusion criteria and PICO (no) - Statement of pre-defined protocol (partial yes) - Comprehensive literature study (partial yes) - Study selection in duplicate (yes) - Data extraction in duplicate (yes) - List of excluded articles (no) - Included studies described in adequate detail (partial yes) - Risk of bias assessment (yes) - Meta-analyse: NA - Conflict of interest (yes)	

CI: confidence interval; FI: fecal incontinence; MA: meta-analysis; Mg: milligram; NA: not applicable; RCT: randomised controlled trail; SLR: systematic literature review; UI: Urine incontinence

Verantwoording Uitgangsvraag 5: gebruik MECC

Inleiding

Uit de knelpuntenanalyse blijkt dat de Europese richtlijn voor Externe katheters bij volwassen mannen (2021) van de European Association of Urology Nurses (EAUN) aansluit bij het veld. Ook werd geconcludeerd dat het verwarring kan opleveren om andere informatie over het gebruik van de MECC te verstrekken als CV&V actief de vertaalde richtlijn promoot. Het integraal overnemen van de vertaalde richtlijn lijkt daarom de beste keuze.

Beoordeling richtlijn EAUN

Om er zeker van te zijn dat de methodologische kwaliteit van de vertaalde EAUN-richtlijn voldoende is, is de Appraisal of Guidelines for Research & Evaluation (AGREE) checklist gebruikt.

Vraag		Score (1-7)	Toelichting
Domein 1. Onderwerp en doel Domeinscore: 94%			
1	Het doel van de richtlijn is specifiek beschreven.	7	Het doel, de te verwachten voordelen en doelgroep zijn duidelijk en uitgebreid beschreven
2	De vraag/vragen die in de richtlijn aan de orde komt/komen, is/zijn specifiek beschreven	7	PICO-vragen zijn opgesteld
3	De populatie (cliënten/algemene bevolking) waarop de richtlijn van toepassing is, is specifiek beschreven.	6	De populatie is beschreven in het methodologie hoofdstuk
Domein 2. Betrokkenheid van belanghebbenden Domeinscore: 61%			
4	De leden van de werkgroep die de richtlijn heeft ontwikkeld, komen uit alle relevante beroepsgroepen.	5	De vijf leden van de werkgroep zijn uitgebreid beschreven in een apart hoofdstuk. De werkgroepleden zijn geschikt en relevant. Er is geen epidemioloog/methodologische expert in de groep, maar een aantal leden hebben relevante ervaring in literatuuronderzoek.
5	Het perspectief en de voorkeuren van de doelpopulatie (cliënten/algemene bevolking), zijn nagegaan	3	Eén patiëntvertegenwoordiger heeft het document beoordeeld tijdens de review proces. Verder zijn de uitkomsten van het proces en gemaakte aanpassingen niet beschreven.

6	De beoogde gebruikers van de richtlijn zijn duidelijk benoemd.	6	De doelgroep is benoemd
Domein 3. Methodologie Domeinscore: 52%			
7	Er zijn systematische methoden gebruikt voor het zoeken naar wetenschappelijk bewijsmateriaal	4	Systematische methoden zijn gebruikt, maar de beschrijving er van is niet altijd helder en niet consistent met het stroomschema van het proces. Ongeveer een derde van de opgenomen bronnen zijn extra toegevoegde artikelen, boeken en websites, die buiten de zoekopdracht gevonden zijn, en waarvan de afkomst niet duidelijk is.
8	De criteria voor het selecteren van het wetenschappelijk bewijsmateriaal zijn duidelijk beschreven.	7	In- en exclusiecriteria zijn duidelijk vermeld, motivering is gegeven voor de selectie van bepaalde criteria
9	De sterke punten en beperkingen van het wetenschappelijk bewijsmateriaal zijn beschreven.	5	Er is gebruikgemaakt van een aangepaste versie van het beoordelingssysteem van het Oxford Centre for Evidence-Based Medicine (OCEBM). Dit systeem lijkt vooral gericht te zijn op onderzoeksdesign, en neemt andere mogelijke methodologische beperkingen niet in acht. Aangezien bijna alle bewijs opgenomen in dit richtlijn toch het laagste bewijskrachtniveau heeft, maakt dit hier niet veel uit.
10	De gebruikte methoden om de aanbevelingen op te stellen, zijn duidelijk beschreven	5	De methoden zijn beschreven, maar niet erg uitgebreid.
11	Gezondheidswinst, bijwerkingen en risico’s zijn overwogen bij het opstellen van de aanbevelingen.	5	Dit is niet goed besproken in het methodologie hoofdstuk, maar gezondheidswinst, bijwerkingen en risico’s worden wel besproken bij de aanbevelingen zelf.
12	Er bestaat een expliciet verband tussen de aanbevelingen en het onderliggende bewijsmateriaal.	4	Dit is niet altijd duidelijk. Achtergrondinformatie en de onderbouwing voor aanbevelingen gaan door elkaar, wat de leesbaarheid en praktische toepasbaarheid van de richtlijn wel vergroot, maar maken dat het moeilijk is om precies te onderscheiden wat de

			bewijsstatements zijn en waar ze vandaan komen.
13	De richtlijn is voor publicatie door externe experts beoordeeld.	2	Dit is erg summier beschreven, de methoden en de resultaten van de beoordeling zijn niet aangegeven.
14	Een procedure voor herziening van de richtlijn is vermeld.	1	Niet vermeld.
Domein 4. Helderheid en presentatie Domeinscore: 94%			
15	De aanbevelingen zijn specifiek en ondubbelzinnig.	6	De aanbevelingen zijn specifiek en ondubbelzinnig.
16	De verschillende beleidsopties zijn duidelijk vermeld.	7	Dit is hier niet echt van toepassing, omdat de richtlijn over een specifiek beleid gaat. Alternatieven worden toch uitgebreid beschreven en er is een beslisboom voor behandeling van urine-incontinentie bij verschillende scenario's.
17	De kernaanbevelingen zijn gemakkelijk te herkennen.	7	Aanbevelingen worden duidelijk gepresenteerd in tabellen.
Domein 5. Toepassing Domeinscore: 46%			
18	De richtlijn beschrijft de bevorderende en belemmerende factoren bij het toepassen van de richtlijn.	6	Bevorderende en belemmerende factoren worden besproken.
19	De richtlijn geeft advies en/of hulpmiddelen voor toepassing van de aanbevelingen in de praktijk.	7	De richtlijn bevat checklists, stroomschema's, figuren en foto's om te toepassing er van te faciliteren in de praktijk.
20	De mogelijke implicaties van het toepassen van de aanbevelingen voor de kosten en benodigde middelen zijn overwogen.	1	Dit wordt niet besproken in de richtlijn, dit zou het beste op lokaal niveau behandeld worden volgens de auteurs.
21	De richtlijn geeft criteria om te toetsen of de richtlijn wordt gevolgd.	1	Dit wordt niet behandeld in de richtlijn.
Domein 6. Onafhankelijkheid van de opstellers Domeinscore: 58%			

22	De opvattingen van de financierende instantie hebben de inhoud van de richtlijn niet beïnvloed.	6	Er is een paragraaf over belangenverstrengeling in de richtlijn.
23	Conflicterende belangen van leden van de richtlijnwerkgroep zijn vastgelegd en besproken.	3	De conflicterende belangen van de werkgroepleden zelf zijn niet expliciet genoemd.

Algemeen oordeel

1	Beoordeel de algemene kwaliteit van de richtlijn.	5	-
2	Ik zou deze richtlijn aanbevelen voor gebruik.	Ja	-

Gebruik vertaalde richtlijn EAUN

De door CV&V vertaalde richtlijn is niet opgesteld in het format dat V&VN gebruikt voor richtlijnen. Om de module herkenbaar te maken als V&VN module is daarom gekozen de richtlijn in een andere volgorde weer te geven dan het document van CV&V. Wel is de inhoud ongewijzigd.

Hoofdstuk in vertaalde richtlijn	In de module
1. Inleiding	Inleiding module – algemene inleiding
2. Methodologie	Deze verantwoording
3. Terminologie	Inleiding module – Terminologie
4. Indicaties, contra-indicaties en alternatieven voor gebruik van een externe katheter bij mannen	Inleiding module – Indicaties, contra-indicaties en alternatieven voor gebruik van een externe katheter bij mannen
5. Complicaties	Aanbevelingen en Samenvatting van de kennis
6. Producten en materialen	Aanbevelingen en Samenvatting van de kennis
7. Uitgangspunten voor verpleegkundige interventies	Aanbevelingen en Samenvatting van de kennis
8. Scholing van verpleegkundigen	Implementatie en Overwegingen
9. Patiëntenvoorlichting	Patiënteninformatie
10. Kwaliteit van leven van de patiënt	Overwegingen
11. Dossiervoering	Aanbevelingen en Samenvatting van de kennis

12. Afkortingen	Algemene lijst van afkortingen in richtlijn
13. Afbeeldingenoverzicht	N.v.t.
14. PICO-vragen	Deze verantwoording
15. Bijlages	In bijlage modules
16. Over de auteurs	Deze verantwoording
17. Literatuur	Algemene literatuurlijst

Verantwoording uit vertaalde EAUN-richtlijn

Methodologie

2.1 Doel en reikwijdte

Het belang van deze richtlijn

De externe katheter voor mannen is een hulpmiddel waarvoor een duidelijke rol is weggelegd bij de behandeling van mannen met UI, maar wordt onvoldoende ingezet, waarschijnlijk door een gebrek aan scholing in het gebruik ervan. Met deze richtlijn willen we het gebrek aan (evidence-based) informatie over het gebruik van dit type katheter aanpakken, en zorgverleners aanmoedigen om in meer gevallen deze behandeloptie te overwegen.

Het overkoepelende doel

Deze richtlijn geeft zorgverleners en cliënten en hun familieleden inzicht in de verschillende stappen die doorlopen worden bij het gebruik van externe katheters voor mannen met UI en bij de daaraan voorafgaande patiëntenbeoordeling. Het doel van de richtlijn is het vergroten van de kennis over externe katheters voor mannen en het geven van praktisch advies over het gebruik ervan.

We hebben deze richtlijn opgesteld om de therapietrouw bij het gebruik van externe katheters voor mannen te bevorderen en onbedoelde nadelige gevolgen voor patiënten te voorkomen. In deze richtlijn hebben we op basis van literatuuronderzoek en consensus binnen de werkgroep het beschikbare wetenschappelijke bewijs of de best practices voor veilig gebruik van externe katheters voor mannen in kaart gebracht. De werkgroep heeft ervoor gekozen om in te gaan op onderwerpen als indicaties, contra-indicaties en alternatieven, verpleegkundige uitgangspunten en interventies bij de toepassing van externe katheters bij mannen, evenals op patiëntenvoorlichting. In deze richtlijn wordt ook vermeld wat er naar boven is gekomen over zaken die van invloed zijn op de kwaliteit van leven (KvL) van de patiënt.

Te verwachten voordelen

Bij aanvang van het schrijfproces werd de reikwijdte van deze richtlijn bepaald. Als leidraad voor het literatuuronderzoek werden er zes PICO-vragen geformuleerd.

We hebben in deze richtlijn duidelijke illustraties, stapsgewijze beschrijvingen van de te verrichten handelingen, en vele literatuurverwijzingen opgenomen. Met de informatie uit deze richtlijn zullen zorgverleners beter in staat zijn om mogelijke probleemgebieden te herkennen bij de patiëntenbeoordeling en het aanbrengen en verwijderen van externe katheters bij mannen.

Concreter gezegd is het de bedoeling dat deze richtlijn zorgverleners zal helpen om complicaties bij het gebruik van externe katheters voor mannen te voorkomen en zal bijdragen aan een betere kwaliteit van leven bij mannen die deze katheters gebruiken. Tot de mogelijke complicaties bij het gebruik van deze katheters behoren UWI's, klachten in verband met irritatie, een allergische reactie of beknelling, en decubitus, andere vormen van huidbeschadiging en lekkage.

We hebben ernaar gestreefd deze richtlijn zo volledig mogelijk te maken. Om de beoordeling en begeleiding van mannelijke patiënten die een externe katheter gaan gebruiken ook daadwerkelijk op de juiste manier te kunnen invullen, zal de verpleegkundige of andere zorgverlener echter ook moeten beschikken over een grondige kennis van de anatomie van de urinewegen en het nodige inzicht in de verpleegkundige grondbeginselen, en in de praktijk bekwaam moeten zijn bevonden in de werkwijze rondom het gebruik van externe katheters bij mannen. Wij verwachten dat deze richtlijn van waarde zal zijn voor mannen met UI die baat kunnen hebben bij (al dan niet uitsluitend) gebruik van een externe katheter.

Beperkingen

De richtlijnenwerkgroep van de EAUN heeft deze richtlijn opgesteld om verpleegkundigen meer inzicht te geven in evidence-based zorg en het gemakkelijker voor ze te maken om de gedane aanbevelingen te implementeren in hun dagelijks werk. Deze richtlijn heeft geen verplicht karakter en het opvolgen van de aanbevelingen garandeert niet dat in alle gevallen een goed resultaat zal worden behaald. Bij het nemen van zorggerelateerde beslissingen zal de zorgverlener altijd per geval moeten bepalen wat de beste keuze is, na te hebben overlegd met de patiënt en met collega's. De zorgverlener dient daarbij gebruik te maken van de beschikbare wetenschappelijke kennis en zijn of haar eigen klinische oordeel.

Samenstelling van het team

De werkgroep die verantwoordelijk is voor deze herziene richtlijn bestaat uit de gespecialiseerde verpleegkundigen Veronika Geng, Susanne Vahr en Hanny Cobussen-Boekhorst. De werkgroep heeft hulp gekregen van Hanneke Lurvink, werkzaam op het hoofdkantoor van de EAUN, en van uroloog Ian Pearce, die geholpen heeft bij het schrijven van de paragraaf 'Indicaties'.

Literatuuronderzoek

De informatie in deze richtlijn is verkregen door middel van een systematisch literatuuronderzoek en door het bestuderen van de huidige werkwijzen in de verschillende landen die lid zijn van de EAUN.

In december 2014 voerde Veronika Geng, een gespecialiseerd verpleegkundige uit Duitsland, de eerste zoekopdrachten uit.

Databases

- Pubmed;
- Cinahl;
- Cochrane.

Zoektermen

- Male external catheters;
- Condom catheters;
- Urinary sheaths;
- External urinary catheter.

In juli 2015 werden er aanvullende zoekopdrachten uitgevoerd door Susanne Vahr, een gespecialiseerd verpleegkundige uit Denemarken.

Databases

- Embase;
- Cinahl;
- Cochrane.

Zoektermen

- Male external catheters;
- Condom catheters;
- Urinary sheaths;
- External urinary catheter;
- Complications.

Door het ontbreken van vaste, door indexeerders toegekende trefwoorden (‘Medical Subject Headings’, MeSH) werd er aan de hand van vrije tekst gezocht naar ‘external catheter’, ‘condom catheter’ en ‘urinary sheaths’.

De zoekresultaten werden niet beperkt tot gerandomiseerde gecontroleerde onderzoeken, gecontroleerde klinische onderzoeken, meta-analyses of systematische reviews. Aanvullende zoekopdrachten werden niet beperkt tot een bepaald bewijskrachtniveau (‘Level of Evidence’, LE). Voor literatuur over praktische zaken rondom het aanbrengen van een externe katheter bij mannen (zie de bijlagen) werd gebruikgemaakt van brochures van fabrikanten

Afbakening van het onderzoeksgebied

Verschillende PICO-vragen die de werkgroep had geformuleerd, dienden als leidraad voor de zoekopdrachten en gegevensverzameling.

In december 2014 werd het onderzoeksgebied afgebakend aan de hand van de volgende criteria:

- geschreven in het Engels;
- volwassen;
- onderzoek bij mensen;
- leeftijd ≥19 jaar;
- 2004-2014.

Toegepaste exclusiecriteria bij het selecteren van abstracts:

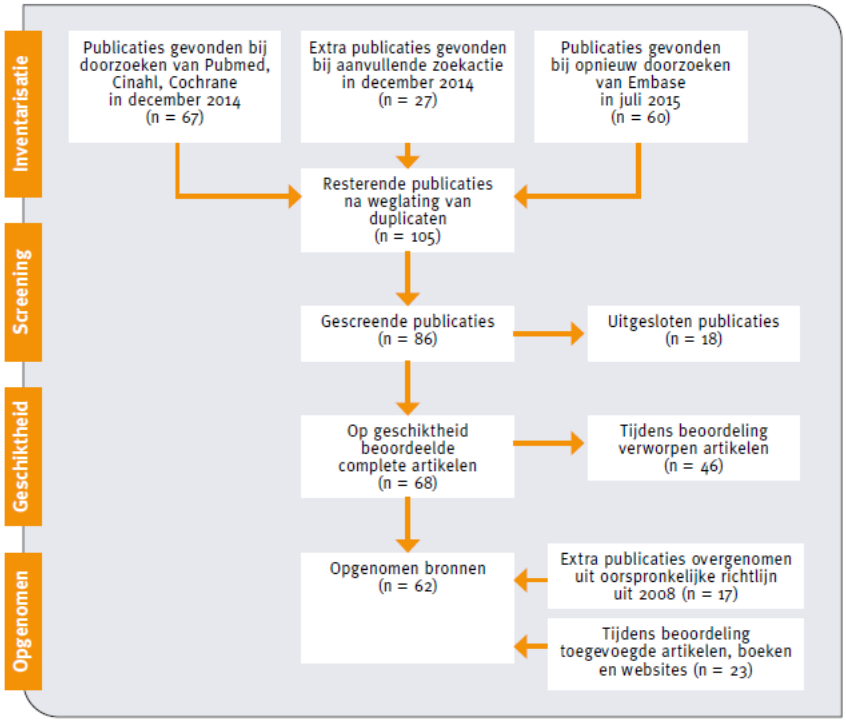
- niet in het Engels geschreven onderzoekspublicaties;
- congrespublicaties;
- onderzoek bij kinderen;
- gebruik van externe katheters bij mannen voor diagnostische doeleinden.

Het was een beleidsmatige beslissing om het onderzoeksgebied op de bovenstaande manier af te bakenen. Na het screenen van de onderzoeksresultaten in december 2014 uitgevoerde zoekopdrachten (waarbij de publicatiedatum moest vallen in de afgebakende periode 2004-2014), werd besloten om ook een zoekactie zonder afgebakende publicatieperiode uit te voeren. Wel werd er voor deze aanvullende zoekactie voor gekozen bij het verzamelen van informatie over complicaties geen gebruik te maken van artikelen die gepubliceerd waren vóór het jaar 2000. Dergelijke artikelen zouden namelijk betrekking kunnen hebben op katheters die vervaardigd waren van materiaal dat tegenwoordig niet meer wordt gebruikt. Publicaties waarnaar verwezen was in de oorspronkelijke versie van de richtlijn (uit 2008), werden na controle ook opgenomen als de tekst geen verandering had ondergaan. Bij het doornemen van de artikelen werden nieuwe literatuurverwijzingen gevonden, en als de betreffende bronnen relevant waren voor het onderwerp en aangehaald werden in de tekst, werden deze aan de literatuurlijst toegevoegd.

Zoekresultaten

De zoekopdrachten leverden de volgende resultaten op:

Stroomschema 1. Literatuuronderzoek voor de richtlijn aanbrengen externe katheter bij volwassen mannen



Belangenverstrengeling

De leden van de richtlijnenwerkgroep van de EAUN hebben vastgelegd welke relaties mogelijk tot belangenverstrengeling zouden kunnen leiden. Deze informatie is opgeslagen in de database van de EAU. De EAUN is een non-profitorganisatie. Ontvangen financiële steun heeft uitsluitend betrekking op administratieve ondersteuning en reis- en vergaderkosten. Er zijn geen honoraria of andere vergoedingen verstrekt. Deze richtlijn is ontwikkeld met financiële steun van Coloplast, Hollister Incorporated en Manfred Sauer GmbH.

2.6 *Beperkingen van dit document*

De EAUN is zich bewust van en aanvaardt de beperkingen van dit document. We vinden het belangrijk om te benadrukken dat de in deze richtlijn verstrekte informatie gericht is op de behandeling van individuele patiënten volgens een gestandaardiseerde aanpak. Het verstrekken van deze informatie dient te worden beschouwd als het doen van aanbevelingen zonder juridische implicaties. De beoogde lezers van deze richtlijn zijn praktiserende verpleegkundigen en andere zorgverleners. Overwegingen ten aanzien van de kosteneffectiviteit kunnen het best op lokaal niveau behandeld worden, en vallen daarom buiten het bestek van deze richtlijn.

2.7 Review proces

Gespecialiseerde verpleegkundigen, urologen uit verschillende landen en een patiëntvertegenwoordiger hebben een geblindeerde beoordeling van dit document uitgevoerd. Daarna heeft de werkgroep op grond van de ontvangen op- en aanmerkingen de richtlijn aangepast, en de relevante (in sommige gevallen na de zoektermijn) aangeleverde bronnen in het document verwerkt. De uiteindelijke versie van dit document is goedgekeurd door het bestuur van de EAUN en door de EAU-manager die verantwoordelijk is voor de activiteiten van de EAUN.

2.8 Beoordelingssysteem

Bij de aanbevelingen in dit document is gebruikgemaakt van een aangepaste versie van het beoordelingssysteem dat in 2011 werd uitgebracht door het Oxford Centre for Evidence-Based Medicine (OCEBM) (OCEBM Levels of Evidence Working Group* 2011). Externe gegevensverzamelaars hebben de gevonden publicaties kritisch beoordeeld aan de hand van het door de EAU gehanteerde systeem voor gegevensverzameling. Waar mogelijk heeft de werkgroep de behandelingsaanbevelingen ingedeeld op basis van een beoordelingsschaal met drie niveaus (aanbevelingsniveau A t/m C), en het bijbehorende bewijskrachtniveau vermeld om lezers een beter beeld te geven van de validiteit van de beweringen. Er is voor deze aanpak gekozen om helderheid te verschaffen over de gedane aanbevelingen en het onderliggende bewijs ervoor. Tabel 1 en 2 maken dit beoordelingssysteem inzichtelijk. Omdat een groot deel van het bewijs zwak bleek te zijn, heeft de werkgroep besloten om aan enkele aanbevelingen een hoger aanbevelingsniveau (‘Grade of Recommendation’, GR) toe te kennen dan in eerste instantie was gedaan. Zulke opgewaardeerde aanbevelingen zijn aangeduid met ‘A*’. Deze aanduiding geeft aan dat de werkgroep in onderling overleg besloten heeft de betreffende aanbeveling te doen ondanks dat er sprake was van bewijskrachtniveau 4.

Bij sommige publicaties was het lastig om een bewijskrachtniveau toe te kennen. Als de werkgroep echter van mening was dat de informatie in de praktijk van pas zou komen, werd bewijskrachtniveau 4 toegekend. Een laag bewijskrachtniveau houdt slechts in dat er op het moment dat de richtlijn werd geschreven in de literatuur geen onderbouwing met een hoger bewijskrachtniveau werd aangetroffen. Het lage bewijskrachtniveau moet dus niet gezien worden als indicatief voor het belang van het betreffende onderwerp of de betreffende aanbeveling voor de dagelijkse praktijk.

De door de werkgroep ontwikkelde richtlijn is bedoeld voor evidence-based verpleegkunde volgens de definitie van Behrens (2004): “een vorm van verpleegkunde waarbij men het nieuwste, meest hoogwaardige wetenschappelijke onderzoek verwerkt in de dagelijkse verpleegkundige praktijk, rekening houdend met de theoretische kennis, de ervaring van de verpleegkundige, de mening van de patiënt en de beschikbare middelen” (Behrens 2004). De aanbevelingen in deze richtlijn zijn tot stand gekomen op basis van het wetenschappelijke bewijs dat de artikelen samen hebben opgeleverd. De werkgroep heeft de tekst zoveel mogelijk gebaseerd op het bewijs uit de artikelen, maar bij het ontbreken daarvan heeft de werkgroep best practices en consensus als uitgangspunt gebruikt.

Er kunnen vier factoren onderscheiden worden die van invloed zijn op een verpleegkundige beslissing: de klinische ervaring van de betreffende verpleegkundige, de middelen die voorhanden zijn, de mening en behoeften van de patiënt, en bevindingen uit de verpleegwetenschap (Behrens 2004). Hieruit volgt dat de literatuur wel belangrijk is, maar dat de ervaring en beleving van de verpleegkundige en de patiënt ook een cruciale rol spelen in het besluitvormingsproces. Een opgestelde richtlijn zal dus niet allesbepalend zijn voor de verpleegkundige praktijk.

Tabel 1. Bewijskrachtniveau (LE)

1a	Bewijs afkomstig uit een meta-analyse van gerandomiseerde onderzoeken
1b	Bewijs afkomstig uit minimaal één gerandomiseerd onderzoek
2a	Bewijs afkomstig uit één gecontroleerd, niet-gerandomiseerd onderzoek met een goede onderzoeksopzet
2b	Bewijs afkomstig uit minimaal één ander type quasi-experimenteel onderzoek met een goede onderzoeksopzet

3	Bewijs afkomstig uit niet-experimentele onderzoeken met een goede onderzoeksopzet, zoals vergelijkende onderzoeken, onderzoeken naar correlaties, en patiënt-controleonderzoeken
4	Bewijs afkomstig uit rapporten of opinies van deskundigencommissies of gebaseerd op de klinische ervaring van autoriteiten op het betreffende gebied en gevalsbeschrijvingen

Tabel 2. Aanbevelingsniveau (GR)

Niveau	Soort bewijs - aard van de aanbeveling
A	Gebaseerd op hoogwaardige klinische onderzoeken die betrekking hebben op de specifieke aanbeveling en waarvan er minimaal één een gerandomiseerd onderzoek is
B	Gebaseerd op deugdelijk uitgevoerde klinische onderzoeken die geen van alle een gerandomiseerd klinisch onderzoek zijn
C	De aanbeveling is gedaan in afwezigheid van rechtstreeks van toepassing zijnde hoogwaardige klinische onderzoeken

Overgenomen van Oxford Centre for Evidence-Based Medicine (OCEBM) (OCEBM Levels of Evidence Working Group* 2011)

PICO-vragen

Volgens het OCEBM “is het stellen van zorgvuldig geformuleerde klinische vragen één van de fundamentele vaardigheden die nodig zijn om evidence-based geneeskunde te kunnen beoefenen. Bij deze vragen is het belangrijk dat ze rechtstreeks relevant zijn voor het probleem van de betreffende patiënt en dat ze u door de manier van formuleren al op weg helpen om relevante en exacte antwoorden te vinden. Een goede vraagstelling zal dus zowel de arts als de patiënt ten goede komen.”

Een zorgvuldig geformuleerde voorgrondvraag dient vier specifieke elementen te bevatten. Het PICO-model helpt bij het opstellen van een gerichte en goed gestructureerde voorgrondvraag die eenvoudig is om te zetten in zoekopdrachten. De afzonderlijke PICO-elementen die de vraag bevat vormen namelijk een handig uitgangspunt bij het bepalen van de zoektermen voor uw literatuuronderzoek.

- P = patiënt/probleem/populatie (Hoe zou u de vergelijkbare groep patiënten/cliënten omschrijven? Wat zijn de belangrijkste kenmerken van de patiënt/cliënt?)
- I = interventie, prognostische factoren, exposure (Naar welke interventie neigt u het meest? Wat bent u van plan met deze patiënt? Wat is de belangrijkste alternatieve interventie die u overweegt?)
- C = ‘comparison’ oftewel vergelijking (er kan ook een vergelijking met niets of met een placebo plaatsvinden) (Wat is de belangrijkste alternatieve aanpak waarmee de interventie vergeleken kan worden? Probeert u een keuze te maken tussen twee geneesmiddelen, tussen een geneesmiddel en geen medicatie of een placebo, of tussen twee diagnostische testen?)

- O = ‘outcome’ oftewel uitkomst (Wat wilt u bereiken, meten, verbeteren of beïnvloeden? Bij uitkomsten kan het gaan om ziektegerelateerd of om patiëntgerelateerd uitkomsten.) (Dahlgren Meml Libr Georg Univ USA 2015).

Het PICO-model voor de richtlijn externe katheter bij volwassen mannen

Onderwerp	
Populatie Aandoening, ernst van de ziekte en ziektestadium, comorbiditeiten & demografische patiëntgegevens	Mannen met urine-incontinentie
Interventie Dosering, toedieningsfrequentie en wijze van toediening	Het gebruik van een externe katheter voor mannen
Vergelijking Placebo, standaardzorg of werkzame vergelijkingsbehandeling	Het gebruik van inleggers of luiers, het niet aanpakken van de incontinentieklachten, het gebruik van een verblijfskatheter of het gebruik van intermitterende katheterisatie
Uitkomst Gezondheidsgerelateerde uitkomsten: morbiditeit, mortaliteit, kwaliteit van leven	Urinewegklachten/kwaliteit van leven/urine-incontinentie, complicaties aan de urinewegen zoals UWI’s, allergische reacties

PICO-vraag 1

Heeft het gebruik van externe katheters voor de behandeling van mannen met UI voordelen of nadelen ten opzichte van het gebruik van andere continentiehulpmiddelen?

PICO-vraag 2

Zijn er aan productkwaliteit of materiaalkenmerken gerelateerde factoren die in verband zijn gebracht met een betere uitkomst ten aanzien van

- het hanteren van de producten
- complicaties
- incontinentiegerelateerde ongelukjes
- de conditie van de huid

PICO-VRAAG 3

Is er bewijs waaruit blijkt dat scholing van verpleegkundigen complicaties kan voorkomen of van invloed is op de resultaten bij mannen die een externe katheter gebruiken?

PICO-VRAAG 4

Met welke zaken moet vóór het aanmeten van een externe katheter voor mannen rekening worden gehouden om de beste continentieresultaten te bewerkstelligen en complicaties te voorkomen?

PICO-VRAAG 5

Is er bewijs over het gebruik van externe katheters voor mannen dat betrekking heeft op de preventie van decubitus, andere vormen van huidbeschadiging, allergische reacties of lekkage?

PICO-VRAAG 6

Is er bewijs over hoe externe katheters voor mannen presteren ten opzichte van andere soorten katheters of over speciale verpleegkundige interventies om UWI's te voorkomen?

Over de auteurs

Veronika Geng, RN MHSc/MNSc (DE), voorzitter

Gediplomeerd verpleegkundige, infectiepreventieverpleegkundige, coach op het gebied van kwaliteit in de gezondheidszorg, master in de gezondheidswetenschappen met als specialisatie verpleegkunde.

Veronika Geng werkt op dit moment als projectleider bij de Manfred-Sauer-Foundation in Lobbach, Duitsland. Ze heeft klinische onderzoeken verricht naar de incidentie van in het ziekenhuis verworven UWI's. Veronika heeft als werkgroeplid meegeholpen bij het opstellen van de eerdere richtlijn over externe katheters voor mannen en heeft een instructievideo over ditonderwerp gemaakt.

Specifieke aandachtsgebieden: voeding, behandeling van blaas- en darmproblemen bij mensen met ruggenmergletsel.

Susanne Vahr, RN PhD-student (DK)

Susanne Vahr werkt als gespecialiseerd verpleegkundige op de urologieafdeling van het academische ziekenhuis Rigshospitalet in Kopenhagen, Denemarken.Ze zit in het bestuur van de EAUN. Daarnaast is ze lid van de Deense vereniging voor urologieverpleegkundigen en zit ze in het bestuur van de Deense onderwijsraad.

Susanne is al sinds 1992 werkzaam binnen de urologie. Ze heeft zich vooral toegelegd op competentieontwikkeling om moderne en goede zorg voor urologische patiënten te waarborgen.

Specifieke aandachtsgebieden: verpleegkundige interventies bij patiënten met blaaskanker en de preventie van UWI's bij patiënten bij wie een blaaskatheter wordt gebruikt.

Hanny Cobussen-Boekhorst, PhD (NL)

Gediplomeerd verpleegkundige en verpleegkundig specialist in continentie- en urostomazorg bij volwassenen en kinderen op de afdeling Urologie van het Radboud UMC in Nijmegen.

Hanny spreekt geregeld op nationale en internationale congressen en is betrokken bij de nationale opleiding tot UCS-verpleegkundige in Nederland. In 2015 heeft ze, in samenwerking met de V&VN-afdeling Continentie Verpleegkundigen en Verzorgenden (CV&V), meegeholpen bij het actualiseren (overeenkomstig de EAUN-richtlijn) van een informatiebrochure voor patiënten over schone intermitterende katheterisatie, waarin ook een protocol voor verpleegkundigen is opgenomen.

Hanny is lid van V&VN Urologie Verpleegkundigen en van de CV&V. Daarnaast is ze lid van de V&VN Stomaverpleegkundigen, de European Society for Paediatric Urology Nurses Group (ESPU-N), en de EAUN.

Speciale aandachtsgebieden: urologische problemen bij patiënten met neurologische problematiek, (kinderen met) spina bifida en blaasextrofie en urotherapie bij kinderen.

Hanneke Lurvink (NL)

Hanneke is sinds 2006 werkzaam voor de EAU. In 2007 werd ze aangesteld als coördinator voor alle EAUN-activiteiten. Ze heeft bijgedragen aan elk van de acht EAUN-richtlijnen die sinds 2007 verschenen zijn, waarbij ze zich heeft beziggehouden met de redactie, het vinden van de juiste illustraties, copyrightkwesties, het literatuuronderzoek, de gegevensverzameling en het opzoeken van volledige publicaties, het ontwerpen van duidelijke stroomschema's, en met de planning en het halen van gestelde deadlines.

Hanneke is lid van het Guidelines International Network.

Ian Pearce (VK)

Ian heeft zijn opleiding gedaan in Nottingham, Stoke en Manchester en werkt sinds 2002 als specialist urologische chirurgie in het Manchester Royal Infirmary in het Verenigd Koninkrijk. Hij is benoemd tot erepenningmeester van de British Association of Urological Surgeons (BAUS) en is hoofdredacteur van het *Journal of Clinical Urology*.

Speciale aandachtsgebieden: blaasdisfunctie & andrologie.

Commentaarfase en aanpassingen

Naar aanleiding van de commentaarfase zijn de volgende punten aangepast:

- Enkele tekstuele wijzigingen zijn gemaakt in de aanbevelingen en de moduletekst ten behoeve van de leesbaarheid.
- In voetnoten is toegevoegd als adviezen niet gelden voor de Nederlandse situatie of als producten/materialen in Nederland slecht verkrijgbaar zijn.

Patient journey persona

Persona 2
Meneer Ramadhin (79)

- *Alleenstaand*
- *Altijd in de bouw gewerkt en is lichamelijk snel zwakker aan het worden*
- *Krijgt wijkverpleging omdat hij niet meer zo makkelijk zichzelf kan aankleden en verzorgen. Ook helpt de thuiszorg met zijn medicatie voor zijn hartproblemen.*
- *De dochter van meneer woont in Suriname en er zijn geen mantelzorgers in de directe omgeving.*
- *Gaat niet meer veel van huis omdat hij niet lang kan lopen of staan.*

- *Heeft last van snel geprikkelde darmen*
- *Geen controle over laten van winden*
- *Is niet altijd op tijd bij het toilet en heeft vaak ongelukjes*