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RANDOMISED CONTROLLED TRIAL

One year effectiveness of an app-based treatment for urinary incontinence in comparison to care as usual in Dutch general practice: A pragmatic randomised controlled trial over 12 months

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Abstract

Objective: To assess the long-term effectiveness of app-based treatment for female stress, urgency or mixed urinary incontinence (UI) compared with care-as-usual in primary care.

Design: A pragmatic, randomised controlled, superiority trial.

Setting: Primary care in the Netherlands from 2015 to 2018, follow up at 12 months.

Population: Women with two or more UI episodes per week and access to mobile apps, wanting treatment. A total of 262 women were randomised equally to app or care-as-usual; 89 (68%) and 83 (63%) attended 1 year follow up.

Interventions: The standalone app included conservative management for UI with motivation aids (e.g. reminders). Care-as-usual was delivered according to the Dutch GP guideline for UI.

Main outcome measures: Effectiveness assessed by the change in symptom severity score (ICIQ-UI-SF) and the change in quality of life (ICIQ-LUTSqol) with linear regression on an intention-to-treat basis.

Results: Clinically relevant improvement of UI severity for both app (-2.17 ± 2.81) and care-as-usual (-3.43 ± 3.6) groups, with a non-significant mean difference of 0.903 (-0.66 to 1.871).

Conclusion: App-based treatment is a viable alternative to care-as-usual for UI in primary care in terms of effectiveness after 1 year.

KEY WORDS

app, effectiveness, eHealth, general practice, long term, pragmatic, primary care, self-management, urinary incontinence

Tweetable abstract: App-based treatment for female urinary incontinence is a viable alternative to care-as-usual after 12 months.

Trial registration: Dutch Trial Register identifier: Trial NL4948 (www.trialregister.nl/trial/4948). The trial was registered before participant inclusion started. Linked article: See related article at <https://doi.org/10.1111/1471-0528.17191>.

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1 | INTRODUCTION

Urinary incontinence (UI) affects one in three women and causes a loss of quality of life. This is compounded by the fact that many women experience barriers to seeking help,¹ and often receive suboptimal care when they seek care from a general practitioner (GP).^{2,3} These factors can lead both to avoidable suffering if symptoms persist and to unnecessarily high costs for society when inadequate treatment results in limited benefit.

An eHealth application for the treatment of incontinence may not only improve care but also reduce costs by offering an accessible and effective standalone strategy. For this reason, we have developed an app to guide the treatment of women with stress, urgency and mixed UI. Although digital content and care-as-usual are delivered differently, the content of the app has been carefully designed to reflect that of relevant Dutch and International guidelines for pelvic floor muscle training and bladder training.^{4,5} In a qualitative study, we showed that this digital approach to content delivery and treatment was appreciated by women, who reported that they expected it to help lower barriers to seeking help, increase self-awareness and provide support with treatment adherence.⁶ Subsequently, in a pragmatic randomised controlled trial, we also confirmed the short-term effectiveness of app-based treatment compared with care-as-usual for treating UI in general practice over 4 months.⁷ In that research, app-based treatment was not inferior to care-as-usual and both treatments produced clinically significant decreases in the severity of incontinence, consistent with the results of two Swedish trials showing the effectiveness of an internet-based programme and mobile app for treating stress UI.^{8,9}

The long-term effectiveness of an eHealth application for all common types of UI has not been compared with care-as-usual. We therefore aimed to assess the long-term effectiveness of our app-based treatment compared with care-as-usual by GPs.

2 | METHODS

2.1 | Study design

We performed a pragmatic, parallel arm, randomised controlled trial of patients with stress UI, urgency UI or mixed UI to compare app-based treatment and care-as-usual in a GP setting. The study design, recruitment challenges and primary outcome (non-inferiority of treatment after 4 months) have been published in detail elsewhere.^{7,10,11} Here, we perform a secondary superiority analysis with a focus on the effectiveness after 12 months.

We recruited adult Dutch women with stress, urgency or mixed UI via general practices, the lay press and social media from July 2015 through to July 2018. The full inclusion and exclusion criteria are presented in Appendix S1. A baseline assessment was performed by a researcher/

GP trainee (AMML and NJW), with participants asked to complete web-based questionnaires and a 3-day frequency-volume chart. Women then underwent physical and urogynaecological examinations.¹² The questionnaires and frequency-volume chart were repeated after 4 and 12 months.

2.2 | Randomisation and blinding

A researcher/GP trainee confirmed eligibility, obtained signed informed consent, collected baseline data and enrolled the participant in the study. Randomisation was performed with the computer program ALEA, which allowed full concealment of group allocation. Participants were randomised with 1:1 allocation and random block sizes were stratified at the GP level.¹⁰ The study design meant that we could not blind participants or care providers to treatment allocation.

2.3 | Interventions

The details of the interventions are outlined in Appendix S1. Women in the intervention group gained access to the URinControl app, the content of which was based on relevant Dutch GP and international guidelines for treating UI.^{4,5} Women in the care-as-usual group were referred to their own GP to discuss treatment options. GPs were advised to follow the Dutch GP guideline on UI, without limitations on the type and mode of treatment.⁴

2.4 | Outcomes

Treatment effectiveness after 12 months was assessed by the change in incontinence symptom severity scores, measured by the International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI-SF), and the condition-specific quality of life (ICIQ-LUTSqol).^{13,14} The minimum important differences for the change of score within the treatment groups have been established as 2.52 (SD 2.56) for the ICIQ-UI-SF and 3.71 (SD 4.69) for the ICIQ-LUTSqol.¹⁵

2.5 | Statistical methods

We assessed treatment effect for superiority between groups by linear regression on an intention-to-treat basis, with results considered statistically significant if the *P* value was <0.05. We compared the following baseline characteristics of the final cohort with those of the group lost to follow up with linear regression and non-parametric tests: age, body mass index, educational level, number of vaginal births, postmenopausal status, recruitment type, duration and type of UI, previous treatment and UI severity. We will

present the number of participants who received the allocated intervention, defined as at least one app-login for the app group, and an actual GP consultation in the care-as-usual group. No statistical analyses were performed. The differences in symptom severity and quality of life outcomes were compared with adjustment for baseline scores of UI severity (UI-SF). Data were analysed with IBM SPSS version 26.0 (IBM Corp., Armonk, NY, USA) and R Studio version 1.2.5033.

3 | RESULTS

In total, 262 eligible women were randomly allocated to app-based treatment ($n = 131$) or care-as-usual ($n = 131$) (Figure 1). The mean age of the included women was 54 years (range 23–86 years) and most (66%, $n = 114$) had moderate UI.¹⁵ Stress UI and more severe UI seemed more common in the care-as-usual group, despite randomisation (Table 1). The 12-month follow-up period ended on 23 September 2019, by which time 89 women (68%) from the app-based treatment group and 83 (63%) from the

care-as-usual group were available for the intention-to-treat analysis.

3.1 | Treatment groups

Women who dropped out ($n = 90$) were younger (mean and standard deviation: 49.9 ± 12.2 years) than those with complete follow up ($n = 172$) (53.5 ± 11.2 years; difference -3.2 , 95% CI -6.6 to -0.7), and had a higher body mass index (27.3 ± 5.2 kg/m² compared with 28.7 ± 5.4 ; difference 1.5, 95% CI 0.2–2.9). We found no other significant differences between the groups (Table S1). We chose not to impute any values because the group with follow-up data was representative and few data were missing. We missed one baseline assessment in the group with follow-up data, which led to missing data on the outcome parameters for 1/172 individuals.

Table 2 shows the interventions received by both treatment groups. In the app group, 96 women (94.1%) received the allocated treatment, compared with 75 women (80.6%) in the care-as-usual group. During the 12-month follow

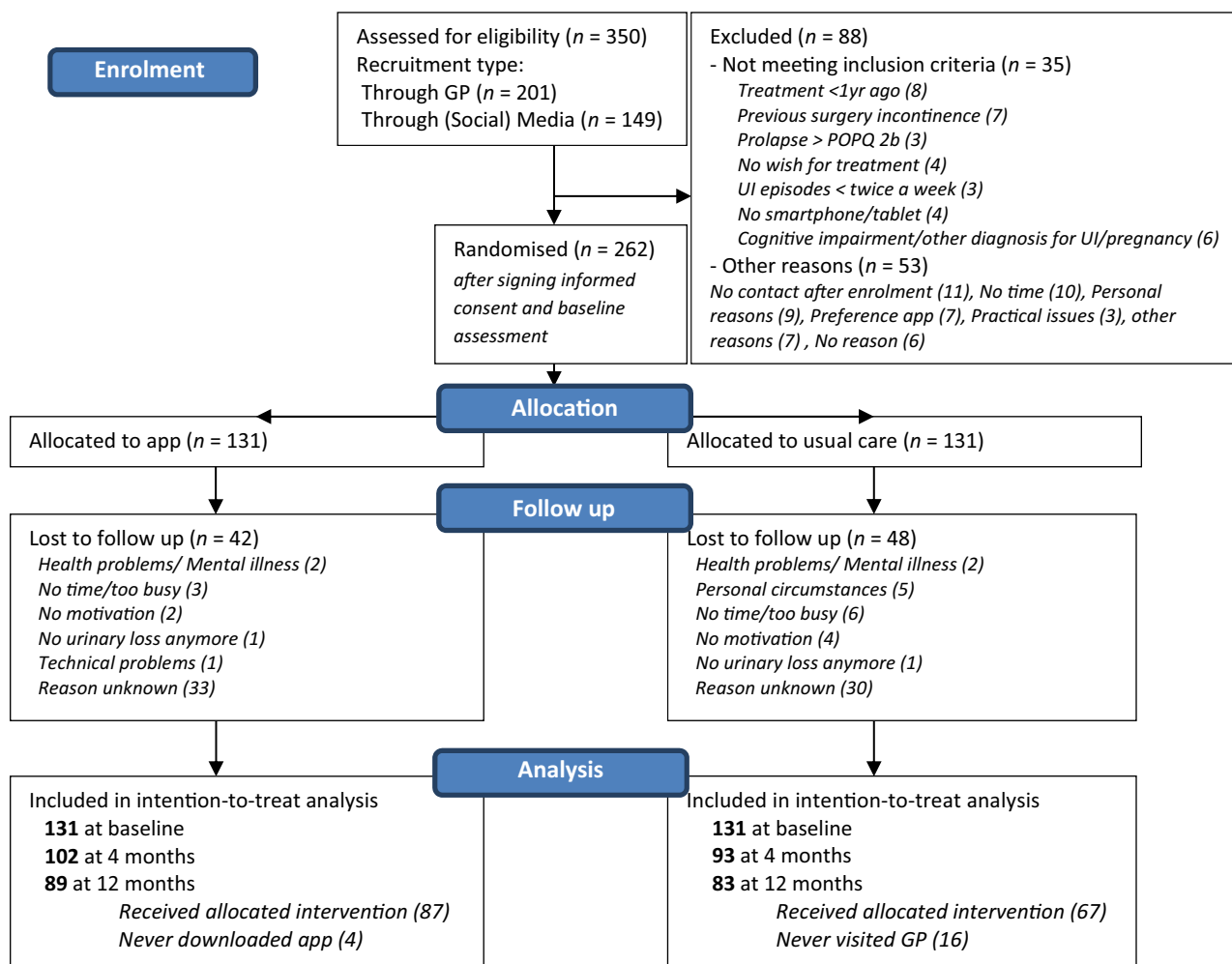


FIGURE 1 CONSORT Flow diagram of participant recruitment. POPQ, Pelvic Organ Prolapse Quantification; UI, urinary incontinence

TABLE 1 Baseline characteristics of women with complete follow-up data shown by treatment group

Characteristics	App-based treatment	N ^a	Care-as-usual	N ^a
Age (years)	54.9 ± 12.2	89	52.0 ± 9.8	83
Higher educational level	43 (51.8%)	83	40 (50.6%)	79
Body mass index (kg/m ²)	26.6 ± 5.0	89	28.0 ± 5.4	83
Duration of UI (years)	8 (4–14)	89	8 (4–14)	83
Type of UI				
Stress	34 (38.2%)	89	36 (43.4%)	83
Mixed, stress predominant	24 (27.0%)		23 (27.7%)	
Urgency	9 (10.1%)		8 (9.6%)	
Mixed, urgency predominant	22 (24.7%)		16 (19.3%)	
Incontinence severity				
ICIQ-UI SF score	9.2 ± 3.0	88	10.5 ± 3.1	83
ICIQ-LUTSqol score	33.1 ± 7.5	88	33.4 ± 7.2	83
Generic quality of life score (EQ-5D-5L)	0.864 ± 0.19	88	0.896 ± 0.17	83
Makes use of incontinence products, yes	69 (80.2%)	86	68 (84.0%)	81
If yes, mean number of products per day	2 (1–4)	69	2 (1–3.75)	68
Previous treatment for UI				
None	67 (75.3%)	89	58 (69.9%)	83
Pessary	–		1 (1.2%)	
Physical therapist	22 (24.7%)		24 (28.9%)	

Note: Values are means ± standard deviation, numbers (%), or medians (interquartile range). Educational level was assessed at follow up.

Abbreviations: ICIQ-UI SF, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; ICIQ-LUTSqol, ICIQ lower urinary tract symptoms quality of life; UI, urinary incontinence.

^aN varied because of missing data of one baseline assessment and three baseline questionnaires.

TABLE 2 Comparison of groups by interventions received during 1 year follow-up

	App-based treatment n = 89 (68%)	Care as usual n = 83 (63.3%)
Received allocated intervention (App-login or visited GP at least once)	87 (97.7)	67 (80.7)
Specific treatment for UI		
Physical therapy for UI	3 (3.4)	15 (18.1)
Medication from GP for UI	–	3 (3.6)
Physical therapy and medication from GP	–	–
Alternative medication for UI	–	–
Physical therapy and medication from GP	–	–
Medication from GP or alternative medication	–	–
Physical therapy, medication from GP, and alternative medication	–	–
Other treatment: pessary (1)/tension-free vaginal tape (1)	–	2 (2.4)

up, seven women (6.9%) in the app group, and 40 women (43.0%) in the care-as-usual group received physical therapy. Respectively, 4 (3.9%) and 5 (5.4%) women received drug

treatment. One of the participants (care-as-usual group) has been referred to secondary care for a tension-free vaginal tape procedure.

3.2 | Effectiveness

Women in both the app-based treatment and care-as-usual groups showed improvements of all symptom scores after 12 months (Table 3). Severity of incontinence improved with by –2.17 (SD 2.8) versus –3.43 (SD 3.6) points, respectively, and the change in condition-specific quality of life improved with –4.66 (SD 5.1) versus –4.34 (SD 5.7), respectively. The change in symptom scores between treatment groups did not differ significantly (Table 4). The adjusted differences in ICIQ-UI-SF score, and ICIQ-LUTSqol score were 0.903 (95% CI –0.66 to 1.871) and 0.445 (–1.125 to 2.015), respectively.

4 | DISCUSSION

4.1 | Main findings

We found no significant difference in change between app-based treatment and care-as-usual, meaning that neither intervention was superior to the other. App-based treatment for women with stress, urgency and mixed UI may therefore

TABLE 3 Questionnaire scores at baseline and follow up comparing app-based treatment and care-as-usual

Outcomes	Questionnaire scores			
	App-based treatment		Care-as-usual	
	Baseline	12 months	Baseline	12 months
	N = 130	N = 89	N = 129	N = 83
ICIQ-UI-SF ^a	9.54 ± 3.2	7.00 ± 3.3	10.3 ± 3.4	7.1 ± 4.3
ICIQ-LUTSqol ^b	33.9 ± 8.3	28.4 ± 6.9	33.4 ± 7.8	29.1 ± 8.0

Note: All data are shown as mean ± SD and on an intention-to-treat basis.

Abbreviations: ICIQ-UI SF, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; ICIQ-LUTSqol, ICIQ lower urinary tract symptoms quality of life.

^aRange, 0–21; higher scores correlate with worse incontinence.

^bRange, 19–76; higher scores correlate with a greater negative impact of incontinence on quality of life.

TABLE 4 Change in questionnaire scores from baseline to 12 months by treatment group, including the adjusted difference between groups

Outcomes	Change in score from baseline		
	App-based treatment N = 88	Care-as-usual N = 83	Adjusted difference (95% CI)
ICIQ-UI SF score	–2.17 ± 2.81	–3.43 ± 3.6	0.903 (–0.66 to 1.871)
ICIQ-LUTSqol score	–4.66 ± 5.1	–4.31 ± 5.70	0.445 (–1.125 to 2.015)

Note: Values are presented as mean ± standard deviation. Analyses were performed on an intention-to-treat basis. All outcome measures and difference were adjusted for baseline scores.

Abbreviations: ICIQ-UI SF, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; ICIQ-LUTSqol, ICIQ lower urinary tract symptoms quality of life.

be an effective alternative to care-as-usual in GP care in this study. After 12 months, both treatments produced clinically relevant changes in the main outcome measures. That is, the mean change over time exceeded the minimal clinically important difference for both outcomes. We noted that the changes after 12 months were slightly higher than the changes reported after 4 months.⁷

4.2 | Strengths and limitations

The main strength of this study is that we compared app-based treatment with care-as-usual. The pragmatic design is considered the reference standard for economic evaluations in health care.¹⁶ Other strengths are the use of patient-centred and validated outcome measures, the 12-month follow-up period, and the inclusion of all common UI types. The latter however, could also be considered a limitation, because the study was underpowered to prove effectiveness in the subgroups. Another limitation that should be considered is the loss to follow up that was associated with higher body mass index.

In our pragmatic trial, we focused on effects rather than adherence to both treatments. We did measure the

self-reported numbers of pelvic floor muscle training appointments, but we did not collect adherence data at a micro-level, for example a training-diary in the care-as-usual group. Unfortunately, our logged data for the app-based treatment group were lost as the result of a technical error. Also, it is very debatable if these adherence-data would give a good depiction of the actual adherence, as a patient could watch an exercise once, and then continue to train without the use of the app, or logging of this training.

4.3 | Interpretation (in light of other evidence)

The initial treatment effect remained clinically relevant after 1 year in both groups without decline of the short-term effect. This was not expected, as long-term adherence to treatment is challenging in UI and treatment effect often declines.²¹ For the app-based treatment, the remaining effect could be explained by the availability of the treatment throughout the year; a participant could stop and start whenever she liked. However, this easy availability of treatment was not the case for the control group, while the remaining effect for this group was comparable. Lastly, we might have selected women that were highly motivated, because women were eligible if they wanted treatment and were excluded if they had a strong preference for one of both treatments.

Our study findings are consistent with those from two Swedish studies comparing an app-based approach with either a postal-based programme or postponed treatment and assessed their cost-effectiveness for stress UI in superiority trials.^{8,9,19,20} In both studies, app- or internet-based treatment appeared to be an effective alternative when managing UI.^{8,9} Notably, those studies did not apply a pragmatic design, which is recommended for any such evaluation.¹⁶ In the pragmatic randomised controlled trial, the control group reflects usual care.¹⁶ Ours is the first study to conduct such a comparison, with the results indicating that app-based treatment is an effective alternative for women with UI who present to general practice.

5 | CONCLUSION

5.1 | Practical recommendations

Based on the outcomes in this study, and the cost-effectiveness described elsewhere in this journal,¹⁷ we believe that app-based treatment is a viable alternative to care-as-usual in general practice. As such, it can be recommended to be used. We expect that the implementation of this treatment will lower barriers to healthcare seeking, as it can be used either as a standalone option or as a tool in blended care (supporting care-as-usual). We do recognise, however, that the latter option has not been studied. Although GPs or physical therapists, specialised in pelvic floor dysfunctions,

can offer the app to women who seek help for UI, there is scope for it to be promoted through (social) media and offered online, allowing it to reach women with UI who may not otherwise seek care.

5.2 | Research recommendations

It will be important to identify the factors associated with treatment success and failure if we are to ensure successful implementation and treatment efficacy. Indeed, clarifying these factors could help to improve the app's content and to ensure that it targets the most appropriate populations. Mixed-methods research could be of benefit,¹⁸ and as such, we are currently preparing a report that combines our quantitative and qualitative results. Additionally, it will be important to evaluate and improve the implementation process continuously by collecting user feedback and evaluating log data. Such additional evaluations are often overlooked in eHealth applications.

We conclude that the app-based treatment for stress, urgency and mixed female UI is an effective alternative to care-as-usual in general practice after 12 months. App-based treatment can therefore be recommended as a viable alternative to care-as-usual in general practice.

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CONFLICT OF INTERESTS

None declared. Completed disclosure of interests form available to view online as supporting information.

AUTHOR CONTRIBUTIONS

AMML collected the data, performed the analysis and wrote the paper. HvdW assisted with the analysis and contributed to writing the paper. NJW collected the data and contributed to writing the paper. JHD designed the study, acquired the funding, and contributed to writing the paper. MCStH contributed to the study design, the app's content, and the writing. MYB assisted in the study design and contributed to writing the paper. KMV assisted with the analysis and contributed to writing the paper. MHB designed the study, acquired the funding, was project leader, contributed to the analysis, contributed to writing the paper, and is the guarantor. The corresponding author attests that all listed authors

meet the authorship criteria and that no others meeting the criteria have been omitted.

ETHICAL APPROVAL

The Medical Ethical Review Board of the University Medical Centre Groningen, Netherlands, approved this study on 12 May 2015 (METc-number: 2014/574). All participants gave written informed consent.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.


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