

University of Groningen

Recruitment through media and general practitioners resulted in comparable samples in an RCT on incontinence

van der Worp, Henk; Loohuis, Anne M M; Flohil, Ilse L; Kollen, Boudewijn J; Wessels, Nienke J; Blanker, Marco H

Published in:
Journal of Clinical Epidemiology

DOI:
[10.1016/j.jclinepi.2019.12.001](https://doi.org/10.1016/j.jclinepi.2019.12.001)

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Final author's version (accepted by publisher, after peer review)

Publication date:
2020

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

van der Worp, H., Loohuis, A. M. M., Flohil, I. L., Kollen, B. J., Wessels, N. J., & Blanker, M. H. (2020). Recruitment through media and general practitioners resulted in comparable samples in an RCT on incontinence. *Journal of Clinical Epidemiology*, 119, 85-91. <https://doi.org/10.1016/j.jclinepi.2019.12.001>

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

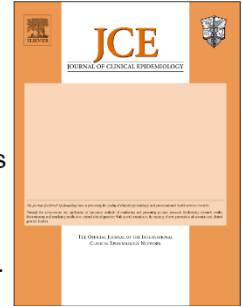
The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Journal Pre-proof



Recruitment through media and general practitioners resulted in comparable samples in an RCT on incontinence.

Henk van der Worp, Anne M.M. Loohuis, Ilse L. Flohil, Boudewijn J. Kollen, Nienke J. Wessels, Marco H. Blanker

PII: S0895-4356(19)30559-1

DOI: <https://doi.org/10.1016/j.jclinepi.2019.12.001>

Reference: JCE 10025

To appear in: *Journal of Clinical Epidemiology*

Received Date: 18 June 2019

Revised Date: 14 November 2019

Accepted Date: 2 December 2019

Please cite this article as: van der Worp H, Loohuis AMM, Flohil IL, Kollen BJ, Wessels NJ, Blanker MH, Recruitment through media and general practitioners resulted in comparable samples in an RCT on incontinence., *Journal of Clinical Epidemiology* (2020), doi: <https://doi.org/10.1016/j.jclinepi.2019.12.001>.

This is a PDF file of an article that has undergone enhancements after acceptance, such as the addition of a cover page and metadata, and formatting for readability, but it is not yet the definitive version of record. This version will undergo additional copyediting, typesetting and review before it is published in its final form, but we are providing this version to give early visibility of the article. Please note that, during the production process, errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

© 2019 Elsevier Inc. All rights reserved.

Recruitment through media and general practitioners resulted in comparable samples in an RCT on incontinence.

Henk van der Worp, Anne M.M. Loohuis, Ilse L. Flohil, Boudewijn J. Kollen, Nienke J. Wessels, Marco H. Blanker

University of Groningen, University Medical Center Groningen, Department General Practice and Elderly Care Medicine, P.O.-box 196, 9700 AD Groningen, The Netherlands

Corresponding author:

Dr. H. van der Worp

Department General Practice and Elderly Care Medicine

University Medical Center Groningen

P.O.-box 196, 9700 AD Groningen, The Netherlands

E-mail: h.van.der.worp@umcg.nl

Phone: +31 50 3615020

Fax: +31 50 3632964

Declarations of interest: none.

Word count: 1819

Abstract

Objective. To assess the impact of recruitment strategy on the baseline characteristics of patients recruited in a randomized controlled trial for treating women with urinary incontinence.

Study Design and Setting. We conducted a cross-sectional analysis of baseline data from an earlier trial. Women were recruited through the media (including social media) or from participating general practices. Baseline characteristics were compared by univariate testing. Logistic regression analysis was performed to study the association between recruitment type and multiple baseline characteristics..

Results. The only differences between recruitment methods were in patient age, with those recruited through the media being significantly older than those recruited through general practice. The mean age difference was 5.0 years (95% confidence interval 2.2–7.9).

Conclusion. Samples recruited through the media and through case identification were largely comparable. Therefore, recruitment through the media may be a viable alternative to recruitment through primary care. This may be especially relevant for research on eHealth treatment for conditions with which patients experience barriers when seeking healthcare.

Keywords

Patient recruitment; Urinary incontinence; eHealth; Primary care; Randomized controlled trial

Running title: Media recruitment versus GP recruitment

1. Introduction

Recruitment in clinical trials is often problematic, with reports indicating that only around 55% of clinical trials succeed in recruiting the prespecified target sample size,[1] and around 11% of all trials involving patients being discontinued because of poor recruitment.[2] This has also been observed in trials in primary care in the Netherlands, where it was shown that almost 40% of projects needed to be extended by at least 50% to obtain the target sample size.[3] [3]When this problem arises, other recruitment strategies may be appropriate, such as recruiting patients via the media, including social media. Indeed, recruitment through (social) media has been found to be cost-effective in studies on mobile health interventions for healthy infant feeding practices,[4] the treatment of heavy-drinking smokers,[5] and weight loss in postmenopausal obese women.[6] However, unequal representation when using different recruitment strategies may lead to the possibility of different baseline characteristics.[7-9] This may have implications for studies on the effectiveness of an intervention and for the generalizability of study results.

We recently conducted a randomized controlled trial (RCT) to assess the non-inferiority of app-based treatment compared to usual care in women with urinary incontinence. In this trial, we had planned to recruit only incident and prevalent cases through general practitioners (GPs).[10] However, despite enough GPs agreeing to participate, we experienced problems because they often recruited no or very few patients. We therefore decided to expand recruitment to include the media, including social media, but we do not know if this sample is comparable to the women who were recruited by GPs. In this research, we aimed to analyze the impact of this change in recruitment strategy on the baseline characteristics of participants in the RCT.

2. Methods

2.1. Study design and recruitment

women. Part of the study involved a pragmatic non-inferiority RCT, for which an extensive description has been published elsewhere.[10] From July 2015 to November 2017 patients were recruited through GPs only, including both incident and prevalent (i.e., non-incident) cases. However, from November 2017 to June 2018, recruitment was done via both GPs and (social) media. All patients gave written informed consent before participating in the study.

Incident and prevalent cases were recruited through 89 participating GPs who agreed to recruit patients for the study. Prevalent cases were approached by letter in 14 of the 30 collaborating practices. The (social) media campaign consisted of the following: interviews in regional newspapers spread through LinkedIn, Facebook, and Twitter; interviews on national and regional radio, as well as local TV; and directed advertisements on Facebook in the study region.

2.2. Baseline characteristics

We collected characteristics during a baseline visit and through an online questionnaire. Medical and gynecological histories were obtained during these visits, and a research physician performed a physical examination to assess pelvic floor activity and prolapse. The online questionnaire assessed the impact of incontinence symptoms (using the ICIQ-UI-SF questionnaire),[11] quality of life (using the EQ-5D-5L, including the EQ-VAS),[12] disease-specific quality of life (using the ICIQ-LUTS-QoL),[13] and the impact of incontinence on sexual functioning (using the PISQ-IR).[14]

2.3. Analyses

Analyses were performed on complete cases with no imputation for missing data because the number of missing values was negligible at baseline. The characteristics of subjects in the two recruitment groups (i.e., GP-recruited and media-recruited cases) were compared by independent t-test or Mann-Whitney U tests for continuous data and by chi-square tests for categorical data, as appropriate.

putative variables were then selected: age, duration of complaints, ICIQ-UI score, type of urinary incontinence (stress or urgency), previous physical therapy for urinary incontinence (yes or no), history of pregnancy (yes or no), and postmenopausal. Multicollinearity between variables was assessed, model fit was assessed by the Hosmer–Lemeshow test and explained variance by the Nagelkerke R^2 .

All analyses were performed using IBM SPSS for windows, Version 25.0 (IBM Corp., Armonk, NY), using a two-sided alpha of 0.05. A Bonferroni correction was applied based on 29 tests resulting in an alpha of 0.002.

3. Results

3.1. Trial recruitment

In total, 262 women were included and randomized, of whom 256 (98%) had complete baseline data and were included for analysis. Thereby the trial met its target sample size of 250 women.[10] Because of a higher than expected loss to follow-up 12 additional women were recruited. The recruitment trajectory of the trial is shown in Figure 1. Recruitment of participants through 89 GPs resulted in the inclusion of approximately 4 participants per month, recruitment through the media resulted in the inclusion of approximately 14 participants per month (Figure 1).

3.2. Differences in baseline characteristics

Among the 108 participants recruited through (social) media, 48 indicated that they had heard about the study through traditional media, 38 through social media, and 22 provided no data on the source. Univariate comparisons among the groups showed a difference only for age (Table 1, $t = -3.495$, $df = 254$, $p=0.001$). The mean difference in age was 5.0 years (95% confidence interval 2.2-7.9).

methods

| | GP recruited | Media recruited | p-value |
|--|-----------------|-----------------|---------|
| | N = 148 | N = 108 | |
| Allocation: intervention/care as usual, N | 75/73 | 54/54 | |
| General characteristics | | | |
| Age (Mean \pm SD) | 50.1 \pm 11.1 | 55.2 \pm 11.8 | 0.001 |
| BMI (Mean \pm SD) | 28.0 \pm 5.4 | 27.2 \pm 5.2 | 0.230 |
| Gynecological history and status | | | |
| Postmenopausal status, N (%) | | | |
| <i>Not postmenopausal</i> | 80 (54.1) | 47 (43.5) | 0.246 |
| <i>Postmenopausal</i> | 63 (42.6) | 56 (51.9) | |
| <i>Unknown due to anticonception</i> | 5 (3.4) | 5 (4.6) | |
| Number of pregnancies, N (%) | | | |
| 0 | 15 (10.1) | 10 (9.3) | 0.832 |
| 1 | 15 (10.1) | 14 (13.0) | |
| 2 | 54 (36.5) | 42 (38.9) | |
| ≥ 3 | 64 (43.2) | 42 (38.9) | |
| Number of vaginal deliveries, N (%) | | | |
| 0 | 25 (16.9) | 17 (15.7) | 0.882 |
| 1 | 21 (14.2) | 15 (13.9) | |
| 2 | 60 (40.5) | 49 (45.4) | |
| ≥ 3 | 42 (28.4) | 27 (25.0) | |
| Hysterectomy, N (%) | 14 (9.5) | 9 (8.3) | 0.756 |
| Other abdominal surgery, N (%) | 51 (34.5) | 40 (37.0) | 0.670 |
| Patient reported feeling of prolapse, N (%) | 13 (8.8) | 5 (4.6) | 0.199 |
| Prolapse (POP-Q stadia), N (%) | | | |
| <i>Stadium 0</i> | 23 (15.5) | 18 (16.7) | 0.197 |
| <i>Stadium 1</i> | 61 (41.2) | 55 (50.9) | |
| <i>Stadium 2A</i> | 64 (43.2) | 35 (32.4) | |
| Pelvic floor functioning, N (%) | | | |
| <i>normal</i> | 45 (30.4) | 38 (35.2) | 0.832 |
| <i>Overactive</i> | 23 (15.5) | 17 (15.7) | |
| <i>Underactive</i> | 79 (53.4) | 53 (49.1) | |
| <i>inactive</i> | 1 (0.7) | 0 (0.0) | |
| Incontinence complaints | | | |
| Duration of urinary incontinence (years; median IQR) | 7 8 | 9.5 15.25 | 0.077 |
| Urinary incontinence type, N (%) | | | |
| <i>Stress incontinence</i> | 61 (41.2) | 46 (42.6) | 0.458 |
| <i>Urgency incontinence</i> | 10 (6.8) | 12 (11.1) | |
| <i>Mixed (stress primary)</i> | 40 (27.0) | 30 (27.8) | |
| <i>Mixed (urgency primary)</i> | 37 (25.0) | 20 (18.5) | |
| Impact of urinary incontinence symptoms (ICIQ-UII SE sum score; mean \pm SD) | 9.6 \pm 3.5 | 10.2 \pm 3.0 | 0.165 |

| | | | |
|------------------------------------|-------------|-------------|-------|
| General | | | |
| EQ-5D-5L, index score (median IQR) | 0.89 0.18 | 0.89 0.18 | 0.618 |
| EQ-VAS (median IQR) | 80 25 | 80 22 | 0.844 |
| Disease specific | | | |
| ICIQ-LUTS-QoL (median IQR) | 31 10 | 32 8.75 | 0.059 |
| urinary incontinence and sexuality | | | |
| PISQ-IR | | | |
| Sexually active, N (%) | 118 (79.7) | 74 (68.5) | 0.041 |
| Not sexually active | N = 30 | N = 34 | |
| <i>NSA-PR</i> | 50 50 | 50 50 | 0.650 |
| <i>NSA-CS</i> | 27.8 66.7 | 16.7 55.6 | 0.504 |
| <i>NSA-GQ</i> | 28.6 50 | 32.1 35.7 | 0.951 |
| <i>NSA-CI</i> | 11.1 36.1 | 5.6 44.4 | 0.983 |
| Sexually active | | | |
| <i>SA-PR</i> | 88.8 22.2 | 77.8 33.3 | 0.278 |
| <i>SA-CS</i> | 66.6 16.7 | 66.6 10.4 | 0.910 |
| <i>SA-GQ</i> | 40 26.7 | 47 28.3 | 0.166 |
| <i>SA-CI</i> | 75 8.3 | 75 16.7 | 0.987 |
| <i>SA-AO</i> | 56.3 18.8 | 56.3 13 | 0.481 |
| <i>SA-D</i> | 50 83.3 | 50 16.7 | 0.217 |

*statistically significant after Bonferroni correction (alpha after correction = 0.002)

Table 2 shows the results of the logistic regression analysis. Duration of symptoms was transformed because of a skewed distribution using a natural log transformation. Again age was the only factor that differed between recruitment types.

Table 2. Results of logistic regression analysis testing the association between multiple baseline

| | Odds ratio for media recruitment | |
|---|----------------------------------|---------|
| | OR (95% CI) | P-value |
| Age | 1.06 (1.03-1.10) | 0.001* |
| Postmenopausal status (ref = not menopausal) | | |
| Postmenopausal | 0.56 (0.24-1.33) | 0.188 |
| Unknown due to anticonception | 1.10 (0.28-4.28) | 0.895 |
| Previous pregnancy (ref = no previous pregnancy) | 0.77 (0.29-2.01) | 0.589 |
| Duration of symptoms (natural log transformation) | 1.26 (0.95-1.67) | 0.104 |
| Type of incontinence (ref = stress incontinence) | 0.76 (0.40-1.43) | 0.397 |
| ICIQ-UI-SF baseline score | 1.06 (0.97-1.15) | 0.207 |
| Previous physical therapy (ref = no physical therapy) | 0.51 (0.28-4.28) | 0.037 |
| Nagelkerke R ² = 0.122 | | |
| Hosmer and Lemeshowtest = 0.467 | | |

*statistically significant after Bonferroni correction (alpha after correction = 0.002)

4. Discussion

4.1. Summary of results.

Different recruitment strategies can lead to differences in the characteristics of recruited samples. In our RCT of app-based treatment for urinary incontinence, however, samples recruited by two different strategies were largely comparable. Indeed, there was only a difference in age between cases recruited through GPs and cases recruited through (social) media, with the latter group being

combining multiple baseline characteristics, age again was the only factor that differentiation between recruitment types.

4.2. Literature.

In this study, recruitment through the media comprised both traditional media (e.g., newspaper items, radio, and TV) and social media (e.g., Facebook, LinkedIn, and Twitter). Although recruitment through the media was almost evenly distributed between traditional and social media, we were unable to compare the two. In a review that compared recruitment by social media to that by other methods, only a few studies were reported to have compared the characteristics of patients recruited by traditional and social media.[15] Of note, it was reported that the relationship with age was contradictory between studies. Two studies of smoking cessation found that subjects recruited through social media were younger than those recruited with traditional methods, such as flyers, newspapers, and word of mouth.[9,16] By contrast, a study on lung cancer screening indicated that there were no age differences between subjects recruited through social media and through newspaper advertisements.[17] In some studies included in the review,[15] differences were found in ethnicity, education level, and socioeconomic status between methods, and it should be noted that these variables were not included in the present study. The authors concluded that recruitment via social media typically led to samples that were not comparable to those recruited by other methods.[15] Nevertheless, this judgment was made on the basis of a difference on a single variable. Another systematic review concluded that recruitment through Facebook led to a group of participants that was representative of traditional methods except for a few minor differences.[18] One difference was that participants were generally younger when recruited through Facebook.

To date, no reviews have identified studies that have directly compared participant characteristics after recruitment through a GP or social media.[15] Indeed, there is only sparse literature comparing recruitment by GPs with recruitment by traditional media. One study of

recruitment methods.[19] Active recruitment (i.e., directly contacting a subject from a defined subject pool) was used in our recruitment of GP cases, whereas passive recruitment (i.e., a general invitation to participate) was used in our media recruitment.[20] The comparison between such active and passive methods of recruitment has been made in other studies. In those focusing on lifestyle interventions, for example, subjects recruited through passive methods had more favorable lifestyles, indicating a selection bias.[20,21] Such bias, indicating a tendency to attract subjects with certain health or disease statuses, was not apparent in the present study.

[22]

4.3. Interpretation of outcomes

The average age difference of 5 years between our study groups was significant, and this finding is particularly relevant for incontinence, which is an age-related condition in which severity increases with age.[23] Therefore, including (social) media cases with a higher age may potentially have resulted in including women with more severe symptoms, yet this was not observed and disease symptoms were comparable between groups. A reason for the difference in age between (social) media cases and GP cases may be that older women do not seek help for their complaints because they assume that the symptoms reflect normal aging.[24] Thus, the older ages among women recruited through the media may reflect a successful public health campaign that accessed more women with erroneous beliefs.

4.4. Limitations

A limitation of this research is that it was not powered for the analyses performed, because the primary aim was to look at the effectiveness of app-based treatment compared to care-as-usual. Another limitation is that relevant comparison variables may not have been measured (e.g., socioeconomic status) because the study was not designed to compare recruitment methods.

4.5. Implications of changing recruitment strategy

(social) media for recruitment was to speed up the recruitment process, the increase in recruitment rate emphasizes that recruitment through (social) media has an important role for women with incontinence, which is a frequent problem for which many women do not seek care despite having significant symptom burdens.[24] Improved attention through (social) media may overcome the barriers to seeking health care for women who experience this problem. However, using such a recruitment strategy changes the target population from women that visit their GP for UI, to also include women that are not in GP records with UI complaints.

4.6. Conclusions

In conclusion, despite a difference in age, recruitment through the media rather than by case identification during consultations had no major impact on the sample that was finally recruited for our study. This will be of particular relevance to future studies given that only a small proportion of women with urinary incontinence seek care through routine consultations,[25,26] which potentially limits sample sizes or necessitates prohibitively long study periods. Recruitment through the media, including social media, could therefore serve as an alternative recruitment strategy to increase study engagement.

Acknowledgments

We thank Dr Robert Sykes (www.doctored.org.uk) for providing editorial services.

Funding: This work was supported by a grant from ZonMw, The Dutch Organisation for Health Research and Development (project number: 837001508) and was sub-funded by a grant from the P.W. Boer foundation. The study won the Professor Huygen award 2016 for best study proposal in general practice, which provided additional funding. These organisations were not involved in the

References

- [1] Sully BG, Julious SA, Nicholl J. A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies. *Trials* 2013;14:166,6215-14-16610.1186/1745-6215-14-166 [doi].
- [2] Kasenda B, von Elm E, You J, Blumle A, Tomonaga Y, Saccilotto R, et al. Prevalence, characteristics, and publication of discontinued randomized trials. *JAMA* 2014;311:1045-5110.1001/jama.2014.1361 [doi].
- [3] van der Wouden JC, Blankenstein AH, Huibers MJ, van der Windt DA, Stalman WA, Verhagen AP. Survey among 78 studies showed that Lasagna's law holds in Dutch primary care research. *J Clin Epidemiol* 2007;60:819-24S0895-4356(06)00434-3 [pii].
- [4] Laws RA, Litterbach EK, Denney-Wilson EA, Russell CG, Taki S, Ong KL, et al. A Comparison of Recruitment Methods for an mHealth Intervention Targeting Mothers: Lessons from the Growing Healthy Program. *J Med Internet Res* 2016;18:e24810.2196/jmir.5691 [doi].
- [5] Bold KW, Hanrahan TH, O'Malley SS, Fucito LM. Exploring the Utility of Web-Based Social Media Advertising to Recruit Adult Heavy-Drinking Smokers for Treatment. *J Med Internet Res* 2016;18:e10710.2196/jmir.5360 [doi].
- [6] Hsu MSH, Harper C, Gibson AA, Sweeting AN, McBride J, Markovic TP, et al. Recruitment Strategies for a Randomised Controlled Trial Comparing Fast Versus Slow Weight Loss in Postmenopausal Women with Obesity-The TEMPO Diet Trial. *Healthcare (Basel)* 2018;6:10.3390/healthcare6030076E76 [pii].
- [7] Adam LM, Manca DP, Bell RC. Can Facebook Be Used for Research? Experiences Using Facebook to Recruit Pregnant Women for a Randomized Controlled Trial. *J Med Internet Res* 2016;18:e250v18i9e250 [pii].
- [8] Stack JA, Paradis CF, Reynolds CF,3rd, Houck PR, Frank E, Anderson B, et al. Does recruitment method make a difference? Effects on protocol retention and treatment outcome in elderly depressed patients. *Psychiatry Res* 1995;56:17-24016517819402617R [pii].
- [9] Frandsen M, Thow M, Ferguson SG. The Effectiveness Of Social Media (Facebook) Compared With More Traditional Advertising Methods for Recruiting Eligible Participants To Health Research Studies: A Randomized, Controlled Clinical Trial. *JMIR Res Protoc* 2016;5:e16110.2196/resprot.5747 [doi].
- [10] Loohuis AMM, Wessels NJ, Jellema P, Vermeulen KM, Sliker-Ten Hove MC, van Gemert-Pijnen JEW, et al. The impact of a mobile application-based treatment for urinary incontinence in adult women: Design of a mixed-methods randomized controlled trial in a primary care setting. *Neurourol Urodyn* 2018;37:2167-7610.1002/nau.23507 [doi].

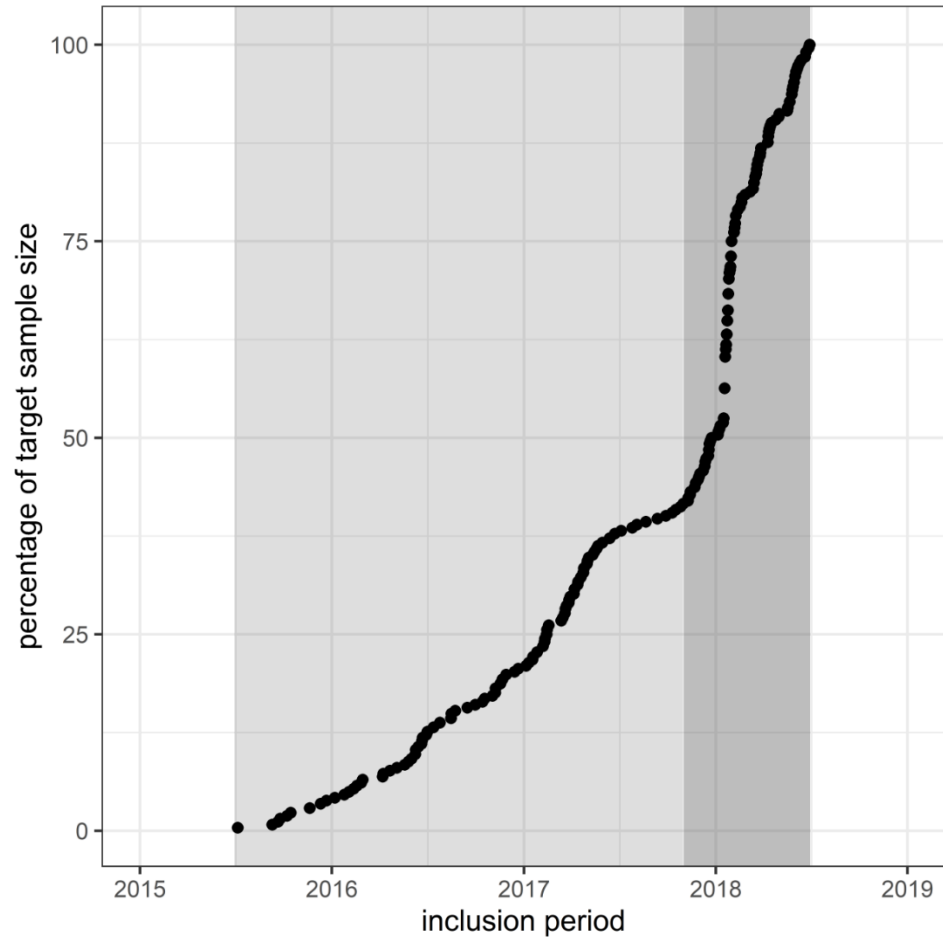
- [12] Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-3610.1007/s11136-011-9903-x [doi].
- [13] Kelleher CJ, Cardozo LD, Khullar V, Salvatore S. A new questionnaire to assess the quality of life of urinary incontinent women. *Br J Obstet Gynaecol* 1997;104:1374-9.
- [14] Rogers RG, Rockwood TH, Constantine ML, Thakar R, Kammerer-Doak DN, Pauls RN, et al. A new measure of sexual function in women with pelvic floor disorders (PFD): the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR). *Int Urogynecol J* 2013;24:1091-10310.1007/s00192-012-2020-8 [doi].
- [15] Topolovec-Vranic J, Natarajan K. The Use of Social Media in Recruitment for Medical Research Studies: A Scoping Review. *J Med Internet Res* 2016;18:e286v18i11e286 [pii].
- [16] Frandsen M, Walters J, Ferguson SG. Exploring the viability of using online social media advertising as a recruitment method for smoking cessation clinical trials. *Nicotine Tob Res* 2014;16:247-5110.1093/ntr/ntt157 [doi].
- [17] Carter-Harris L, Bartlett Ellis R, Warrick A, Rawl S. Beyond Traditional Newspaper Advertisement: Leveraging Facebook-Targeted Advertisement to Recruit Long-Term Smokers for Research. *J Med Internet Res* 2016;18:e11710.2196/jmir.5502 [doi].
- [18] Whitaker C, Stevelink S, Fear N. The Use of Facebook in Recruiting Participants for Health Research Purposes: A Systematic Review. *J Med Internet Res* 2017;19:e29010.2196/jmir.7071 [doi].
- [19] Fleming J, Kamal A, Harrison E, Hamborg T, Stewart-Brown S, Thorogood M, et al. Evaluation of recruitment methods for a trial targeting childhood obesity: Families for Health randomised controlled trial. *Trials* 2015;16:535,015-1062-x10.1186/s13063-015-1062-x [doi].
- [20] Sarkin JA, Marshall SJ, Larson KA, Calfas KJ, Sallis JF. A comparison of methods of recruitment to a health promotion program for university seniors. *Prev Med* 1998;27:562-71S0091-7435(98)90327-9 [pii].
- [21] Manjer J, Elmstahl S, Janzon L, Berglund G. Invitation to a population-based cohort study: differences between subjects recruited using various strategies. *Scand J Public Health* 2002;30:103-1210.1080/14034940210133771 [doi].
- [22] Warren FC, Stych K, Thorogood M, Sharp DJ, Murphy M, Turner KM, et al. Evaluation of different recruitment and randomisation methods in a trial of general practitioner-led interventions to increase physical activity: a randomised controlled feasibility study with factorial design. *Trials* 2014;15:134,6215-15-13410.1186/1745-6215-15-134 [doi].
- [23] Melville JL, Katon W, Delaney K, Newton K. Urinary incontinence in US women: a population-based study. *Arch Intern Med* 2005;165:537-42165/5/537 [pii].
- [24] Visser E, de Bock GH, Kollen BJ, Meijerink M, Berger MY, Dekker JH. Systematic screening for

[25] Schreiber Pedersen L, Lose G, Hoybye MT, Jurgensen M, Waldmann A, Rudnicki M. Predictors and reasons for help-seeking behavior among women with urinary incontinence. *Int Urogynecol J* 2018;29:521-3010.1007/s00192-017-3434-0 [doi].

[26] O'Donnell M, Lose G, Sykes D, Voss S, Hunskaar S. Help-seeking behaviour and associated factors among women with urinary incontinence in France, Germany, Spain and the United Kingdom. *Eur Urol* 2005;47:385,92; discussion 392S0302-2838(04)00502-0 [pii].

Figure captions:

Figure 1. Recruitment trajectory of the trial over time. During the first part of the trial participants were recruited through GPs only (light gray area). During the last part of the trial participants were also recruited through the media (dark gray area).



Abstract accepted for ICS annual conference, September 2019**Hypothesis/aims of the study**

Only around half of all clinical trial succeed in recruiting enough participants to meet the originally specified sample size. In case of problematic recruitment, other strategies may be chosen, such as recruiting participants through social media or lay press. However, applying a different recruitment strategy may lead to sampling bias. This may impair the interpretation of the intervention outcomes and the generalizability of the study results.

We conducted a Randomized Controlled Trial (RCT) comparing an app-based treatment for women with urinary incontinence with usual primary care. We recruited both incident and prevalent cases through general practitioners, but experienced sincere problems with recruitment. We therefore decided to expand to (social) media approaches. To allow a proper interpretation of the generalizability of the outcomes, we analyzed the impact of recruitment strategy on the baseline characteristics of the participants in this RCT.

Study design, materials and methods

We are performing a mixed-methods study on the impact of a mobile application for urinary incontinence in adult women. Part of the study is a pragmatic randomized-controlled non-inferiority trial. Patients were only recruited through GPs from July 2015 to June 2018 (both incident and prevalent cases) and through both (social) media and GPs from November 2017 to June 2018.

The (social) media campaign consisted of interviews in regional newspapers spread through LinkedIn, Facebook and Twitter, interviews on national and regional radio and local broadcasting and directed advertisements on Facebook in the study region.

We collected characteristics through an online questionnaire, and during a baseline visit, consisting of medical history taking and a physical examination. The questionnaire assessed impact of incontinence symptoms (ICIQ-UI-SF questionnaire), quality of life (the EQ-5D-5L including the EQ-VAS) and disease specific quality of life (ICIQ-LUTS-QoL).

Analyses were performed on complete cases without imputation of missing data, because the number of missing values on baseline was expected to be limited.

Baseline characteristics of subjects in the three recruitment groups (incident cases, prevalent cases

correction was applied to control for multiple comparisons. In case of a significant difference, a post-hoc test was performed to identify which recruitment groups differed.

Results

Two-hundred-sixty-two subjects were randomized of which 256 (98%) subjects had complete baseline data and were included for this analysis. Of these, 120 were incident cases, 28 were prevalent cases and 108 were recruited through (social) media. Univariate between group comparisons showed only difference for age (Table 1, $F=9.0$, $df=2$, $p<0.001$). Post-hoc analyses showed that patients recruited through (social) media were significantly older than incident cases (mean difference 6.1 years (95% CI 2.5 to 9.7)) but that prevalent cases did not differ from the other two groups. No differences were found between groups in BMI, gynecological history and status, incontinence complaints, duration of incontinence and quality of life.

Interpretation of results

In this RCT on treatment of female urinary incontinence we found that samples recruited with different strategies were to a large extent comparable. Women included through the social media campaign were considerably older than women invited through general practices. However, this difference in age was not reflected in differences in age related outcomes such as symptom severity, type of urinary incontinence, menopausal status and quality of life.

Concluding message

Using different methods for recruiting women with urinary incontinence did not lead to large differences in characteristics of recruited samples in this study. Therefore recruitment through social media may be considered as a good alternative to other methods when recruiting women with urinary incontinence. This may overcome the barrier that many women experience in seeking help for this important health problem.

