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Osteoarthritis and Cartilage

Effect of the dr. Bart application on healthcare use and clinical outcomes in people with osteoarthritis of the knee and/or hip in the Netherlands; a randomized controlled trial

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SUMMARY

Objective: To evaluate the short-term effects of use of the dr. Bart app, compared to usual care, on the number of secondary health care consultations and clinical outcomes in people with knee/hip OA in the Netherlands.

Method: A randomized controlled design involving participants ≥50 years with self-reported knee and/or hip OA recruited from the community. The number of secondary health care consultations (primary outcome) and secondary outcomes were assessed at baseline, 3 and 6 months via online questionnaires. Data were analyzed using longitudinal mixed models, corrected for baseline values. Due to the design of this study, blinding of participants and researchers was not possible.

Results: In total, 427 eligible participants were allocated to either the dr. Bart group ($n = 214$) or usual care ($n = 213$). We found no difference between groups in the number of secondary (i.e., orthopaedic surgeon, rheumatologist, or physician assistant) health care consultations (incidence rate ratio (IRR) 1.20 (95% CI: 0.67; 2.19)). We found positive treatment effects of the dr. Bart app on symptoms (2.6 (95% CI: 0.4; 4.9)), pain (3.5 (95% CI: 0.9; 6.0)), and activities of daily living (2.9 (95% CI: 0.2; 5.6)) on a 0–100 scale, higher score indicating less complaints, but not in any other secondary outcome.

Conclusion: The dr. Bart app did not change the number of secondary health care consultations compared to usual care. However, we found small positive effects (not clinically relevant) on pain, symptoms, and activities of daily living in people with knee/hip OA.

Trial registration: Dutch Trial Register (Trial Number NTR6693/NL6505) (https://www.trialregister.nl/trial/6505).

Knee and hip osteoarthritis (OA) are among the most prevalent forms of disability worldwide[1,2]. Knee and/or hip OA cause pain and functional disability and have a major impact on quality of life[2–5]. As a result, the personal and societal burden of OA is high[6,7]. In the Netherlands health care costs attributable to OA spent in secondary care (i.e., orthopaedic surgeon, rheumatologist, or physician assistant) are eight times higher than costs spent in primary care (e.g., general practitioner or physical therapist)[8]. As the prevalence of OA increases with age[2,9], it is expected that the burden of OA will increase dramatically in the near future due to the increase in life expectancy, with an extra demand on health services as a consequence[2].

Current treatment of OA is predominantly symptomatic and focuses on controlling pain and improving function and health-

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related quality of life[10–13]. Although total joint arthroplasty is considered a (cost-)effective treatment for people with OA, it should be considered only after conservative treatment (i.e., education, promotion of lifestyle changes, pain management, exercise therapy, and weight reduction in case of overweight) has failed[12,14–16]. Despite recommendations about the content of non-surgical treatment options in OA, quality of care in OA in primary care is suboptimal[15,17,18], resulting in underutilization of non-surgical treatment options and untimely referrals to secondary health care in people with OA[12,15] . This suboptimal use of care could be improved by promoting self-management in people with OA[5,12,14,19]. Self-management interventions offer patients guidance in improving their skills regarding management of symptoms, treatment, and physical and psychological consequences, as well as to improve skills to navigate the health care system[20,21].

Health education and goal setting are considered fundamental elements of effective self-management interventions[22–25]. Goal setting is a widely used behavioral change technique[25] that is associated with positive effects on behavior in both the short and long term[25,26]. Monitoring of behavior or outcomes, providing direct feedback, and getting rewards may augment the effects of goal setting[25]. Thus, self-management interventions augmented with providing feedback and getting rewards may help patients to take better care of their illness and make optimal use of health care options.

Modern persuasive technologies (e.g., applications) offer the possibility to enhance goal setting and provide tailored information to people with OA that suits individual preferences. This enhances self-management at all times[27,28]. Moreover, modern technologies can monitor health behavior and provide real-time feedback, which are considered important elements of self-management[21,29]. The use of modern technologies seems promising and can support patients in taking an active role in the management of their chronic condition in daily life. However, most eHealth applications have not been evaluated in clinical trials[30–34], especially in the field of OA.

Given the high potential of modern technologies to enhance self-management 24/7, we developed an e-self-management application that promotes self-management and supports people with OA to optimize the use of non-surgical treatment options: dr. Bart app. The dr. Bart app is a fully automated eHealth application based on the Fogg model for behavioral change[35], also known as the “tiny habits method”, and augmented with reminders, rewards, and self-monitoring to reinforce app engagement and health behavior. According to the tiny habits method, people with low motivation need an easy objective and a simple trigger to incorporate the target behavior in daily life. The central feature of the app is a library of predefined “tiny habit” goals and triggers to a healthier lifestyle, for instance, “I will perform two squats after brushing my teeth” or “During my lunchbreak I eat an apple rather than an unhealthy snack”. The dr. Bart app proposes a list of five pre-formulated goals to a healthier lifestyle, based on machine learning techniques fed by data collected in a personal profile and previous choosing behavior of the app user; i.e., previously selected and discarded goals. We assumed that use of the app promotes health behaviors, better self-management, and optimal use of non-surgical treatment options, ultimately resulting in better coping with symptoms and fewer secondary health care consultations. The primary objective of this randomized controlled trial (RCT) was to evaluate the short-term effects (after 3 and 6 months) of use of the dr. Bart app (*ad libitum*), compared to usual care, on secondary health care in people with knee/hip OA in the Netherlands. Secondary objectives were to examine the short term effects on clinical outcomes (e.g. pain, physical functioning) attributable to the dr. Bart app in people with knee and/or hip OA.

Methods

Trial design and setting

This was a monocenter, stratified (main OA location; i.e. knee or hip), prospective, unblinded, RCT comprising one intervention group (dr. Bart app) and one control group (usual care) with an allocation ratio of 1:1, conducted in the Netherlands. We examined the effectiveness of the dr. Bart app on the number of self-reported consultations in secondary health care over half a year. Details of the development of the intervention and trial design have been published elsewhere[36]. This study was conducted alongside a controlled clinical trial in Germany. The results of this controlled clinical trial will be reported separately. Moreover, we will report the results regarding use, usability of the dr. Bart app and its relation with clinical outcomes as well as on the cost-effectiveness analysis in two other manuscripts. There were no changes to methods/design after the trial commenced. Ethical approval for this study was asked for and waived by the local Medical Research Ethics Committee of the Radboud University Medical Centre, Nijmegen Commissie Mensgebonden Onderzoek (CMO Arnhem-Nijmegen, Protocol Number: 2017—3625). The study fell outside the remit of the law for Medical Research Involving Human Subjects Act and was approved by the local ethical committee. This study is registered in the Dutch trial register (Trial NL 6505 (NTR6693)). This trial is reported according to the CONSORT-EHEALTH checklist.

Recruitment and screening procedure

This study was conducted at the Department of Rheumatology of the Sint Maartenskliniek Nijmegen (the Netherlands) from January 2018 to January 2019. All participants in this RCT were recruited in the community through advertisements in local newspapers (i.e. region Nijmegen, the Netherlands) and in campaigns on social media of the Sint Maartenskliniek (i.e. Facebook, twitter, LinkedIn). Individuals with OA in the community willing to participate, were invited to the website (www.drbart.eu) to complete several questions to check their eligibility for this RCT. Eligible individuals were asked to sign in for the study by providing their e-mail address on the website. Potential participants received online baseline assessment via CastorEDC (https://www.castoredc.com/). CastorEDC is an electronic software application for data collection and management. CastorEDC is approved with ISO 27001 and ISO9001 and is in line with the European Union (EU) Data Protection Directive.

Participants

Participants were included under the following circumstances: 1) having self-reported OA of the knee and/or hip (i.e. having a painful knee and/or hip, knee and/or hip pain >15 days of the past month, morning stiffness <30 min (knee) and/or < 60 min (hip)); 2) being $\geq$ 50 years age; 3) having an e-mail address; 4) possessing a smartphone or tablet and willing to download the dr. Bart application on one or more devices; and 5) being able to read, write, and sufficiently communicate in Dutch.

Exclusion criteria were as follows: 1) being wheelchair bound, 2) having a diagnosis of (other) inflammatory rheumatic disease, 3) having knee and/or hip replacements and 4) having scheduled for knee and/or hip joint arthroplasty in the next 6 months.

Randomization and blinding

Patients were allocated to the intervention group or control group (allocation ratio 1:1) by the researcher (TP) with CastorEDC after completing baseline assessment. CastorEDC is an electronic software application for data collection and management. Randomization on the individual level was stratified by main OA-location (knee or hip) with randomly varying block sizes of two, four, and six, performed with CastorEDC. The researcher who ascertained randomization was concealed for treatment allocation. After allocation, participants in the intervention group received an e-mail from the researcher (TP) with information to access the dr. Bart app. Participants allocated to the control group received an e-mail that they were assigned to the control group. Due to the design of this RCT, blinding of participants and researchers was not possible. Throughout the study participants were able to call and send mails to the researcher when they had questions regarding the dr. Bart app or the study.

Intervention (dr. Bart app)

The theoretical framework and development process of the dr. Bart app and its pilot test are published elsewhere[36]. The overall goal of the dr. Bart app is to enhance self-management and to actively involve people with OA in managing their own disease. The dr. Bart app is a standalone eHealth application which invites users to select pre-formulated goals (i.e. "tiny habits") and triggers to a healthier lifestyle. The pre-formulated goals are based on four themes that are core elements in the (non-surgical) management of OA: education regarding OA and its treatment modalities and the benefits of a healthy lifestyle, physical activity (both generic and OA specific information), vitality, and nutrition[12–14] . In the education library users can find specific information regarding OA and its treatments modalities, as well as generic lifestyle advice. Moreover, an exercise library is incorporated in the app, containing 10 exercises that are important for the treatment of OA. Users can select or discard goals; the app will continue with proposing goals until three goals are selected by the user. Once one or more goals are completed, the app will propose new goals. Proposed goals are based on machine learning techniques fed by data collected in a personal profile and previous choosing behavior of the app user, i.e. previously selected and discarded goals. In this way, the proposed goals are tailored to the user and suit their personal preferences. To reinforce app engagement and health behavior, the dr. Bart app is augmented with motivation enhancing techniques; reminders, rewards, and self-monitoring, Fig. 1. Users receive a daily push notification to remind them of their chosen goal, combined with an interesting fact or answer to frequently asked question[36].

Participants allocated to the intervention group had the ability to use the dr. Bart app (version 1.3.7.) "*ad libitum*". The app was only accessible for users after the researcher (TP) provided access to the app. The content and functionalities of the dr. Bart app were frozen during the RCT. However, bug fixes (e.g. failure to log in) and system failures were resolved.

Usual care

Half of the participants were allocated to the usual care group and received no active treatment. Usual care is defined as non-standardized care initiated by the participant (self-medication, self-referral) to non-medical professionals or initiated by the general practitioner (after consultation initiated by the participant). Health care providers of participants of neither study group were not informed about the study. Participants in the control group were also offered the dr. Bart app after they fulfilled the last follow-up questionnaire.

Outcomes

Participants received validated online questionnaires at baseline, after 3 and 6 months of follow-up, and, a reminder was sent after a week, where applicable. Participants did not receive (financial) incentives or other compensation for completion of the questionnaires or the study. In cases of missing data on the primary outcome participants were asked to record the number of visits to a secondary health care provider (i.e. orthopedic surgeon, rheumatologist, or physician assistant) via an additional e-mail. Demographic data was collected at baseline. A detailed description of outcome measures is given in a design article[36].

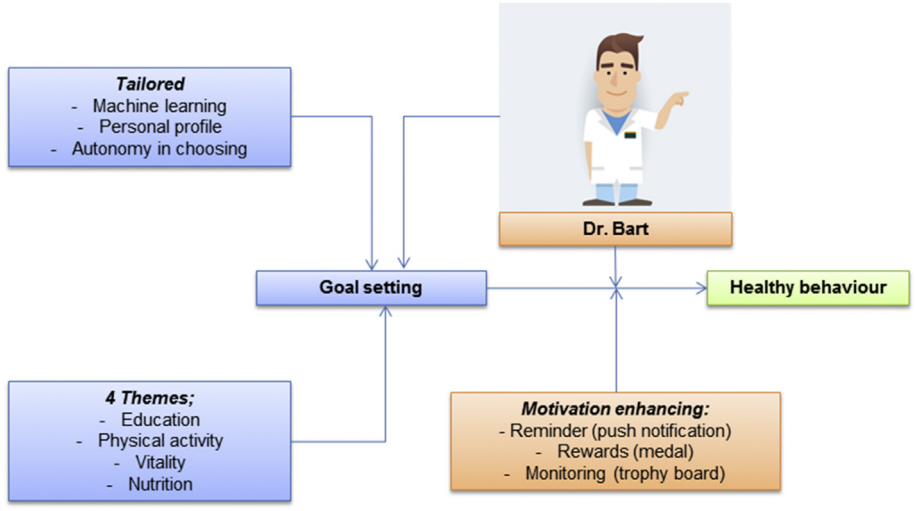

Fig. 1 Theoretical framework of the dr. Bart app.

Primary outcome measure

The primary outcome was the difference in the number of self-reported consultations in secondary healthcare (i.e. orthopaedic surgeon, rheumatologist, physician assistant) due to OA in the knee/hip over the previous 6 months (assessed with a 3-month recall period) between groups, reported as an incidence rate ratio (IRR).

Secondary outcome measures

To evaluate the effectiveness of the dr. Bart app, several self-administered questionnaires were used. We assessed health care utilization with a self-developed questionnaire with a 3 month recall period. Participants were asked to record the number of visits to predefined primary (e.g. general practitioner and physical therapist) and secondary (i.e. orthopedic surgeon, rheumatologist, or physician assistant) health care providers in the preceding 3-month period because of their knee or hip symptoms. Pain, symptoms, and functional limitations were assessed with either knee/hip OA outcome Score (KOOS or HOOS), where appropriate, with a standardized score being presented per sub scale (0–100; higher scores reflecting better health status)[37,38]. Health-related quality of life was assessed with the Euro Quality of Life (EQ-5D-3L) (0–1; higher score reflects better health)[39]. From the Short Questionnaire to Assess Health-enhancing physical activity (SQUASH), we calculated the time spent in light, moderate, and, vigorous intensity per week[40]. Knowledge, skills, and confidence to cope with ones own health were assessed with the Patient Activation Measure (PAM-13) questionnaire[41]. We used the brief Illness Perception Questionnaire (IPQ) to measure patient's cognitive and emotional perceptions with respect to their OA (0–80); higher scores indicate more threatening views of OA[42]. Moreover, quantitative data about the use of the app was automatically extracted from the back end of the dr. Bart app to determine which participants to be included in our per protocol analysis. As described in our protocol paper, we measured costs, treatment beliefs in OA, system usability scale and quality indicators of OA care as well. These outcomes will be reported in separate manuscripts on costs and the comparison between the Netherlands and Germany.

Sample size

Based on previous research[43], an *a priori* sample size of 322 participants (161 per group) would provide 80% power at 5% level of significance (two-sided unpaired *t*-test) to detect a mean difference of 0.35 (standard deviation 1.00) in the number of consultations in secondary health care between groups, anticipating a maximum loss to follow-up of 20%, assuming a normal distribution.

Statistical analysis

All statistical analyses were performed using Stata 13.1 (www.stata.com). Missing data was managed according to the recommendations of the specific questionnaire. For the PAM, we also calculated a total score when a maximum of two items of the questionnaire were missing, though the PAM recommend to only calculate a total score if no single item is missing. For this, we calculated the mean score of the answered questions in the PAM questionnaire and multiplied this by 13. We assessed the percentage of missing data only in participants who were not lost to follow up. Baseline differences between groups were not statistically tested. Primary analyses were performed according to the intention-to-treat principle (ITT). Secondary analyses included per protocol analysis, including adherent participants of the dr. Bart app group (i.e. who chose at least one goal) and the entire usual care group. Descriptive statistics were used to present group characteristics. Selective attrition was checked by comparing baseline characteristics of respondents to baseline characteristics of dropouts at both follow-up points.

According to the recommendations of Twisk *et al.* about missing data in longitudinal mixed-model analyses, no imputation techniques were used[44]. Differences in the primary and secondary outcomes between the dr. Bart app group and usual care group after 3 and 6 months were assessed with either negative binominal regression (number of visits to health care professional) or linear mixed models (measures of self-management behavior, physical activity, quality of life, illness perceptions, and subscales of HOOS/KOOS), with random intercept, treatment group (dr. Bart app or usual care), baseline value, and interaction between treatment group and time as covariates, without random slope. In the mixed models analyses regarding the HOOS and KOOS, main OA-location (knee or hip) was added as covariate. To evaluate whether the proportion of secondary health care health visits (yes/no) was different between groups, we performed a generalized estimating equation using binomial distribution, reporting an odds ratio. Per-protocol analyses were adjusted in the same manner. The primary outcome measure is reported as an IRR with 95% confidence interval (CI).

Results

Participants

In total 692 people were assessed for eligibility in this trial (Fig. 2). A total of 427 participants were allocated to either the intervention group (dr. Bart) ($n = 214$) or the control group (usual care) ($n = 213$). The response rates for the follow-up questionnaires were 75.4% (intervention group, $n = 150$; control group, $n = 172$) and 69.3% (intervention group, $n = 130$; control group, $n = 166$) at 3 and 6 months, respectively. We did not find relevant differences on baseline characteristics between those who filled out the follow-up questionnaires and those who did not fill out questionnaires at follow-up (see Appendix 1a+b). We defined adherence as choosing at least one goal in the dr. Bart app. Subsequently, we considered 151 (70.6%) participants adherent with the dr. Bart app and 63 (29.4%) participants non-adherent. The percentage of missing data on the primary outcome was 0.7%, 3.7% and 5.4% at baseline, and at 3 and 6 months of follow-up, respectively.

The mean age of participants was 62.1 years (SD 7.3), with the majority being female (71.7%) and having symptoms predominantly in the knee(s) (73.3%). Among the participants, 58% experienced their OA symptoms for less than 5 years (Table I).

Primary outcome

Table II depicts health care use of the intervention and control group. We did not find a difference in the primary outcome measure, i.e., the number of secondary health care consultations over 6 months (IRR: 1.20 (95% CI: 0.67; 2.16), intervention group compared to control group).

Secondary outcomes

We did not find a difference in the proportion of participants (yes/no) that consulted a secondary health care provider over 6 months odds ratio (OR (1.24 (95% CI: 0.74; 2.06), intervention group compared to control group)). In both groups, consultations with a physical therapist were most common. We did not find differences in the number of consultations with other health care providers between groups over 6 months (Table II).

Table III shows the results of secondary outcomes at baseline and 3 and 6 months of follow-up. We found a difference in positive

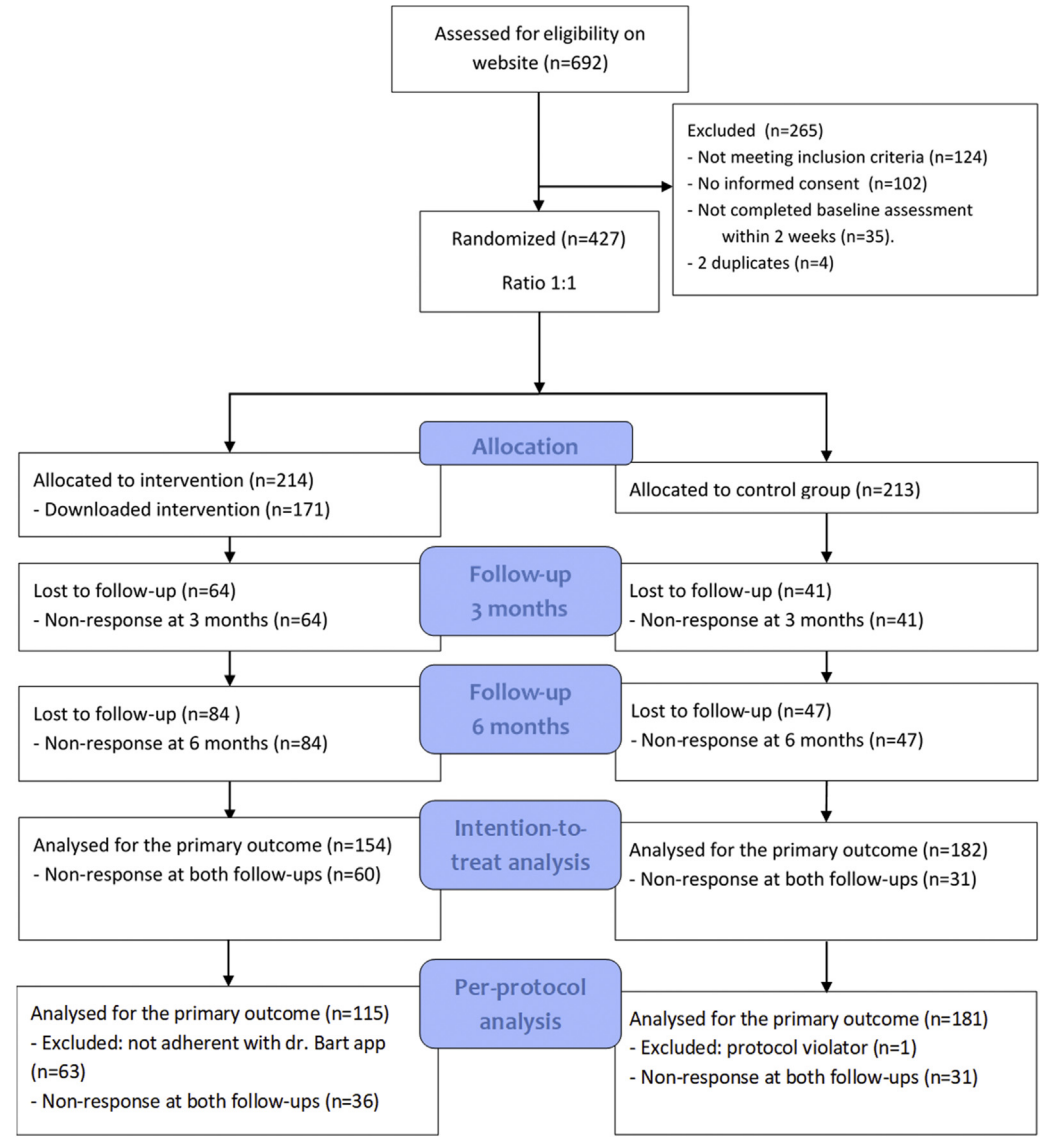

Fig. 2 Flow diagram of participant inclusion in the trial.

changes in symptoms (2.6 (95% CI: 0.4; 4.9)) over 6 months in favor of the intervention group. Moreover, we found differences in positive changes for pain (3.5 (95% CI: 0.9; 6.0)) and activities of daily living (2.9 (95% CI: 0.2; 5.6)) in favor of the intervention group over 6 months. We did not find differences between groups in other secondary outcome measures. Treatment effects between groups at 3 and 6 months are reported in Appendix 1.

Per-protocol analysis

One participant in the control group reported in the follow-up questionnaire to have rheumatoid arthritis. Therefore, this participant was considered a protocol violator and was excluded from the per-protocol analysis. In the intervention group, we considered 63 participants non-adherent and 151 participants adherent (i.e., who chose at least one goal) with the dr. Bart app and these 63 participants were excluded in the per-protocol analysis, Fig. 2.

	Dr. Bart app group ($n = 214$)	Control group ($n = 213$)
Age, years; mean (SD)	62.1 (7.7)	62.1 (7.0)
Female, *n*(%)	147 (68.7)	159 (74.7)
Body Mass Index, kg/m^2; mean (SD)	27.8 (5.1)	27.3 (4.8)
Living together with partner and/or family, *n*(%)	161 (78.9)	168 (84.2)
Years of education (≤12 years), *n*(%)	56 (28.0)	36 (18.6)
OA diagnosed by health care professional		
Yes, *n* (%)	206 (96.3)	198 (93.0)
Main OA-location		
Knee, *n*(%)	157 (73.4)	156 (73.2)
Duration of symptoms, *n*(%)		
< 1 year	25 (11.7)	15 (7.0)
1–5 years	104 (48.6)	102 (47.9)
5–10 years	49 (22.9)	53 (24.9)
> 10 years	36 (16.8)	43 (20.2)

Abbreviations: SD, Standard Deviation; *n*, number; OA, osteoarthritis.

Table I Baseline characteristics of participants allocated to the intervention and control group (n = 427)

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Measures	Dr. Bart group (N = 214)				Control group (N = 213)				Treatment effect of dr. Bart app
	Baseline N = 214	3 months N = 150	6 months N = 130	Mean number of consultations during follow-up (SD)[∞]	Baseline N = 213	3 months N = 172	6 months N = 166	Mean number of consultations during follow-up (SD)[∞]	Δ overall (95% CI)
Consultations in secondary health care, total number (%[‡])	116 (29.6)	54 (20.4)	59 (23.3)	0.73 (1.60)	137 (32.7)	83 (23.8)	72 (19.4)	0.84 (1.82)	1.20* (0.67; 2.16)
Consultation in secondary care? Yes (%[†])	63 (29.6)	29 (20.4)	28 (23.3)	N/A	69 (32.7)	40 (23.8)	31 (19.4)	N/A	1.24† (0.74; 2.06)
Consultations with GP, total number (%[‡])	116 (37.5)	63 (28.8)	45 (24.6)	0.91 (1.67)	105 (43.0)	65 (28.1)	59 (24.2)	0.81 (1.49)	1.24* (0.82; 1.89)
Physical therapist, total number (%[‡])	575 (56.3)	360 (46.6)	329 (46.5)	5.00 (7.56)	611 (49.4)	545 (45.3)	538 (38.2)	6.70 (10.71)	1.05* (0.58; 1.90)

Abbreviations; GP, General Practitioner; ITT, Intention to treat; *n*, number; CI, confidence interval; N/A, not applicable.
* Incidence rate ratio (Negative binomial regression) corrected for baseline values.
† Odds ratio (generalized estimating equation) corrected for baseline values.
‡ denotes the percentage of (non-missing) participants having at least one consultation,
∞ *denotes the mean number of consultations per (non-missing) participant during follow-up.*

Table II Health care use and proportion of patients who visited a health care provider at baseline, at 3 and 6 months per group, and mean treatment effect (95% CI) between groups over 6 months

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We found comparable results in the per-protocol analyses regarding our primary and secondary outcome measures (Appendix 3).

Use of the app

Of the 214 participants allocated to the intervention group, 171 (80%) opened the app at least once. Of all participants, 151 (71%) chose at least one goal. A total of 113 (53%) participants achieved at least one goal. Altogether, more than 9,000 goals were achieved over half a year. For people active with completing goals ($N = 113$), the median length of use was 144 interquartile range (IQR: 63; 173) days, with a median of 33 (IQR: 16; 89) logins per user. A total of 56 (26%) of all participants allocated to the intervention still used the app (i.e. logged in) after 26 weeks.

Discussion

The aim of this RCT was to study the short term effectiveness of the dr. Bart app, compared to usual care, on secondary health care, in people with knee/hip OA in the Netherlands. The results of this RCT show that use of the dr. Bart app, based on the "tiny habits" method, does not change the number of consultations for OA in secondary health care compared to usual care. Moreover, we found

Measures	Dr. Bart group (N = 214)			Control group (N = 213)			Treatment effect of dr. Bart app*
	Baseline mean (SD) N = 214	3 months mean (SD) N = 150	6 months mean (SD) N = 130	Baseline mean (SD) N = 213	3 months (SD) N = 172	6 months (SD) N = 166	Δ overall* (95% CI
Self-management behavior (range 13–52)	40.8 (5.3)	41.2 (5.2)	40.7 (5.4)	40.2 (5.7)	40.6 (6.1)	39.8 (5.5)	0.7 (-0.2; 1.6)
PA, total hours/week	31.6 (21.2)	33.1 (22.4)	26.5 (17.6)	26.6 (18.3)	29.0 (20.7)	26.3 (18.1)	1.1 (-2.2; 4.4)
MVI, hours/week	18.2 (18.7)	18.2 (15.3)	14.6 (11.6)	14.8 (14.3)	17.2 (16.5)	26.3 (14.3)	0.2 (-2.1; 2.6)
Health related quality of life (0–1)	0.72 (0.19)	0.73 (0.18)	0.71 (0.20)	0.71 (0.21)	0.73 (0.19)	0.70 (0.23)	0.00 (-0.03;0.03)
Health related quality of life (slider) (0–100)	70.9 (15.5)	69.2 (17.5)	70.6 (18.1)	69.8 (16.9)	71.2(15.5)	68.7 (17.6)	−1.7 (-4.5; 1.0)
Illness Perceptions (range 0-80)	43.1 (8.9)	41.6 (10.5)	40.8 (10.3)	42.2 (10.4)	41.3 (9.7)	41.0 (9.2)	−0.7 (-2.3; 0.8)
Symptoms†	57.7 (16.3)	57.3 (18.2)	57.3 (17.7)	57.0 (18.9)	56.2 (19.2)	55.2 (19.4)	**2.6 (0.4; 4.9)***
Pain†	57.5 (15.5)	59.5 (16.5)	59.4 (17.7)	58.2 (17.8)	57.4 (18.0)	57.5 (18.0)	**3.5 (0.9; 6.0)***
Activities of daily living†	58.5 (19.7)	61.4 (19.3)	62.1 (20.8)	59.4 (20.2)	58.5 (19.6)	58.6 (19.3)	**2.9 (0.2; 5.6)***
Activities†	32.6 (23.9)	31.9 (22.3)	33.4 (25.0)	32.5 (23.1)	33.2 (25.0)	33.2 (23.4)	1.9 (-2.0; 5.9)
Quality of life†	38.0 (17.5)	39.2 (17.0)	39.1 (18.3)	38.3 (17.1)	38.3 (17.1)	40.5 (15.8)	0.3 (-2.5; 3.1)

Abbreviations; ITT, Intention to treat; *n*, number; PA, physical activity; MVI, moderate-vigorous-intensity.
* Linear mixed models analyses corrected for baseline values.
† Assessed with either KOOS or HOOS.

Table III Mean scores of secondary outcomes at baseline, at 3 and 6 months per group, and mean differences (95% CI) between groups over 6 months

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no significant differences in healthcare utilization (HCU), health-related quality of life, physical activity, self-management behavior or illness perceptions between the intervention and control group over half a year. However, the dr. Bart app is effective with respect to symptoms, pain, and activities of daily living, although these benefits were small.

We found that the dr. Bart app did not have an impact on HCU in patients with knee/hip OA over 6 months. A possible explanation could be that the impact of our eHealth intervention on HCU might take longer than 6 months; it is conceivable that the "tiny habits"[35] will be further incorporated in daily life by participants in following months, and the accumulation of these tiny habits will result in larger health benefits and changes in HCU patterns over time. Self-management aims to increase the capacity of patients to cope with symptoms and managing their care, including skills navigating the health care system. The dr. Bart app stimulates the use of conservative treatment options. We assumed that better self-management will result in change in health care utilization patterns (i.e. optimal use of primary care services and less use of secondary health care services). Previous studies show that the self-management programmes did influence HCU, i.e. postpone total joint replacement surgery in OA patients[45,46]. We chose, however, for a shorter follow-up because of the rapidly evolving nature of eHealth. Future research is needed to assess long-term effects of use of the dr. Bart app.

We found small but significant positive effects on symptoms, pain, and activities of daily living attributable to the dr. Bart app. Although the importance of self-management programs is underlined by international recommendations, there is no consensus on the size of a clinically meaningful effect of (e−)self-management programmes. Effects of the dr. Bart app on pain, function, and symptoms are comparable with more intensive (traditional) self-management programmes in OA[47]. Thus, considering the non-invasive character of the intervention and the unlikeness of harmful effects, we think the positive effects found in this RCT could be worthwhile for patients with knee/hip OA.

We found that 20% of participants allocated to the intervention group did not download the app, while they were willing to participate in eHealth research. Moreover, we considered 30% to be non-adherent with the app. This could indicate a lack of engagement of participants or user-friendliness for the app itself. However, these rates are in line with studies on standalone eHealth applications assisting patients with OA in their preparation for the first consult with an orthopaedic surgeon, which could be used one or 2 weeks prior to consultation[48,49]. So, compared to other standalone eHealth interventions, our rates are comparable[50]. Nevertheless, we found mean (SD) usability scores of the app at 3 and 6 months of follow-up of 68.6 (16.5) and 69.2 (16.9), meaning that it does not reach an acceptable score (i.e. 70); thus, there is room for improvement of the app, which in turn might improve usage.

Currently, RCTs are considered the gold standard for evaluating interventions. It is well-known that executing a RCT is time and money-consuming. This in contrast to the rapidly evolving nature of eHealth interventions. Logically, the design to evaluate these eHealth interventions should reflect this iterative process. Recently, several frameworks have been proposed in the evaluation of eHealth interventions, but these novel frameworks are not commonly applied in practice by researchers[51]. It could be valuable to explore the possibilities of the use of these novel frameworks in the continuous evaluation of eHealth interventions.

To the best of our knowledge, this is the first RCT examining the effectiveness of a standalone (self-management) eHealth application in people with knee/hip OA. Studies on stand-alone eHealth in other chronic diseases (e.g. chronic pulmonary disease, heart failure, and diabetes) showed positive results on disease management, clinical outcomes, and health behavior changes among others (e.g. reduction of hospitalization and improving quality of life)[30,34]. Nevertheless, these reviews concluded that methodological quality of included studies is low, and thus the evidence of efficacy of standalone eHealth is very limited.

The current study has several limitations that should be taken into account when interpreting the results. First, an unavoidable issue in this respect is the lack of blinding of participants. Moreover, loss to follow-up was high at 3 and 6 months in both groups, even though we sent newsletters just before participants received follow-up questionnaires to stimulate response rates. It is conceivable, that the lack of face to face contact could have resulted in the relatively high loss to follow-up[52]. In addition, our study might have been underpowered. We assumed a normal distribution of the number of consultations in secondary care in our sample size calculation, because to the best of our knowledge, there is no generally accepted method to calculate the sample size for negative binomial regression analysis. However, as our analyses were based on considerably more participants than anticipated, it is unlikely that we failed to detect an effect that was present (Type II error). Interestingly, loss to follow-up was higher in the intervention group than in the control group. A possible explanation could be that in the control group the participants were offered the dr. Bart app after completing the last questionnaire. However, we found no differences in baseline characteristics between respondents and dropouts. Finally, the association between intensity of use of the intervention and clinical outcomes is not taken into account in this study[53], this will be further investigated in a future in-depth analysis.

Although effects of the intervention were not clinically relevant, but considering the non-invasive nature of the intervention, the low costs and the safety of the intervention, we think that implementation and further development of the dr. Bart app is worthwhile. The dr. Bart app incorporates treatments of first choice in knee/hip OA; education, lifestyle advice, and healthy behaviors[12,15,19,54]. Our baseline characteristics are similar to participants included in previous OA research. Moreover, we used a mixture of recruitment strategies, resulting in a heterogeneous group of people with OA and guaranteeing the external generalizability of this study. Taking this in mind, the app could be applied as primary approach for the treatment of OA in clinical practice as it has the potential to serve as a trustworthy tool to provide education and goal setting regarding OA and its treatment options.

We showed that use of an e-self-management intervention (dr. Bart app) did not impact HCU compared to usual care over 6 months, but did result in small, albeit not clinically relevant positive effects on pain, symptoms, and activities of daily living in people with knee/hip OA. Additional research is needed to identify possible subgroups of patients who benefit most. Future research is necessary to replicate these results and to determine whether the dr. Bart app is more effective in the long term.

Ethics approval and consent to participate

Ethical approval for this study was asked for and waived by the local Medical Research Ethics Committee of the Radboud University Medical Centre, Nijmegen (Protocol Number: 2017–3625). The study fell outside the remit of the law for Medical Research Involving Human Subjects Act and was approved by the local ethical committee. This study is registered in the Dutch trial register (trial number: NTR 6693). All participants gave digital consent to participate in the present study.

Availability of data and material

The datasets used and/or analyzed in the present study are available from the corresponding author on reasonable request.

Authors' contributions

TP, KB, JvdP, FHJvdH, and CHMvdE participated in the design of the study. TP was responsible for inclusion and data collection. TP, JvdP, and CHMvdE were responsible for data analysis, tables and figures. All authors were responsible for interpretation of data. TP and CHME were responsible for drafting the manuscript, all other authors critical reviewed the manuscript. Furthermore, all authors approved the final version of the manuscript.

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Conflict of interest

The authors declare that they have no competing interests.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.joca.2020.02.831.

References

1. Allen KD, Golightly YM. State of the evidence. Curr Opin Rheumatol 2015;27(3):276–83, https://doi.org/10.1097/BOR.0000000000000161.
2. Cross M, Smith E, Hoy D, Nolte S, Ackerman I, Fransen M, *et al.* The global burden of hip and knee osteoarthritis: estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis 2014;73(7):1323–30, https://doi.org/10.1136/annrheumdis-2013-204763.
3. Stubbs B, Hurley M, Smith T. What are the factors that influence physical activity participation in adults with knee and hip osteoarthritis? A systematic review of physical activity correlates. Clin Rehabil 2015;29(1):80–94, https://doi.org/10.1177/0269215514538069.
4. WHO Scientific Group on the Burden of Musculoskeletal Conditions at the Start of the New Millennium. The burden of musculoskeletal conditions at the start of the new millennium. World Health Organ Tech Rep Ser 2003;919:23–7, http://www.ncbi.nlm.nih.gov/pubmed/14679827.
5. Bennell KL, Hunter DJ, Hinman RS. Management of osteoarthritis of the knee. BMJ 2012;345, https://doi.org/10.1136/bmj.e4934. e4934.
6. Kingsbury SR, Gross HJ, Isherwood G, Conaghan PG. Osteoarthritis in Europe: impact on health status, work productivity and use of pharmacotherapies in five European countries. Rheumatology 2014;53(5):937–47, https://doi.org/10.1093/rheumatology/ket463.
7. Hunter DJ, Schofield D, Callander E. The individual and socio-economic impact of osteoarthritis. Nat Rev Rheumatol 2014;10(7):437–41, https://doi.org/10.1038/nrrheum.2014.44.

8. Volksgezondheidenzorg.info. Artrose. RIVM Bilthoven 2019, https://www.volksgezondheidenzorg.info/onderwerp/artrose. Accessed February 22, 2019.
9. Deshpande BR, Katz JN, Solomon DH, Yelin EH, Hunter DJ, Messier SP, *et al*. Number of persons with symptomatic knee osteoarthritis in the US: impact of race and ethnicity, age, sex, and obesity. Arthritis Care Res (Hoboken). 2016;68(12): 1743–50, https://doi.org/10.1002/acr.22897.
10. Jamtvedt G, Dahm KT, Christie A, Moe RH, Haavardsholm E, Holm I, *et al*. Physical therapy interventions for patients with osteoarthritis of the knee: an overview of systematic reviews. Phys Ther 2008;88(1):123–36, https://doi.org/10.2522/ptj.20070043.
11. Altman RD. Early management of osteoarthritis. Am J Manag Care 2010;16(2):S41–7, http://www.ncbi.nlm.nih.gov/pubmed/20297876.
12. Fernandes L, Hagen KB, Bijlsma JWJ, Andreassen O, Christensen P, Conaghan PG, *et al*. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. Ann Rheum Dis 2013;72(7):1125–35, https://doi.org/10.1136/annrheumdis-2012-202745.
13. Bannuru RR, Osani MC, Vaysbrot EE, Arden NK, Bennell K, Bierma-Zeinstra SMA, *et al*. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthr Cartil 2019;27(11):1578–89, https://doi.org/10.1016/j.joca.2019.06.011.
14. Hochberg MC, Altman RD, April KT, Benkhalti M, Guyatt G, McGowan J, *et al*. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care Res (Hoboken) 2012;64(4):465–74, http://www.ncbi.nlm.nih.gov/pubmed/22563589.
15. Smink AJ, van den Ende CHM, Vliet Vlieland TPM, Swierstra BA, Kortland JH, Bijlsma JWJ. "Beating osteoARThritis": development of a stepped care strategy to optimize utilization and timing of non-surgical treatment modalities for patients with hip or knee osteoarthritis. Clin Rheumatol 2011;30(12):1623–9, https://doi.org/10.1007/s10067-011-1835-x.
16. Ferket BS, Feldman Z, Zhou J, Oei EH, Bierma-Zeinstra SMA, Mazumdar M. Impact of total knee replacement practice: cost effectiveness analysis of data from the Osteoarthritis Initiative. BMJ 2017;356:j1131, https://doi.org/10.1136/bmj.j1131.
17. Porcheret M, Jordan K, Jinks C. Primary care treatment of knee pain - a survey in older adults. Rheumatology 2007;46(11): 1694–700, https://doi.org/10.1093/rheumatology/kem232.
18. Østerås N, Jordan KP, Clausen B, Cordeiro C, Dziedzic K, Edwards J, *et al*. Self-reported quality care for knee osteoarthritis: comparisons across Denmark, Norway, Portugal and the UK. RMD Open 2015;1(1), https://doi.org/10.1136/rmdopen-2015-000136. e000136.
19. Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, *et al*. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthr Cartil 2008;16(2): 137–62, https://doi.org/10.1016/j.joca.2007.12.013.
20. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Counsel 2002;48(2):177–87, http://www.ncbi.nlm.nih.gov/pubmed/12401421.
21. Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. Ann Behav Med 2003;26(1): 1–7, https://doi.org/10.1207/S15324796ABM2601_01.
22. Lenzen SA, Daniëls R, van Bokhoven MA, van der Weijden T, Beurskens A. Disentangling self-management goal setting and action planning: a scoping review. Lavoie K, ed. PLoS One 2017;12(11), https://doi.org/10.1371/journal.pone.0188822. e0188822.
23. Locke EA, Latham GP. Building a practically useful theory of goal setting and task motivation. A 35-year odyssey. Am Psychol 2002;57(9):705–17, https://doi.org/10.1037/0003-066X.57.9.705.
24. Scobbie L, Dixon D, Wyke S. Goal setting and action planning in the rehabilitation setting: development of a theoretically informed practice framework. Clin Rehabil 2011;25(5): 468–82, https://doi.org/10.1177/0269215510389198.
25. Epton T, Currie S, Armitage CJ. Unique effects of setting goals on behavior change: systematic review and meta-analysis. J Consult Clin Psychol 2017;85(12):1182–98, https://doi.org/10.1037/ccp0000260.
26. Samdal GB, Eide GE, Barth T, Williams G, Meland E. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. Int J Behav Nutr Phys Activ 2017;14(1):42, https://doi.org/10.1186/s12966-017-0494-y.
27. Demiris G, Afrin LB, Speedie S, Courtney KL, Sondhi M, Vimarlund V, *et al*. Patient-centered applications: use of information technology to promote disease management and wellness. A white paper by the AMIA knowledge in motion working group. J Am Med Inf Assoc 2008;15(1):8–13, https://doi.org/10.1197/jamia.M2492.
28. Huygens MWJ. A Patient Perspective on eHealth in Primary Care: Critical Reflections on the Implementation and Use of Online Care Services 2017.
29. Bolle S, van Weert JCM, Daams JG, Loos EF, de Haes HCJM, Smets EMA. Online health information tool effectiveness for older patients: a systematic review of the literature. J Health Commun 2015;20(9):1067–83, https://doi.org/10.1080/10810730.2015.1018637.
30. Byambasuren O, Sanders S, Beller E, Glasziou P. Prescribable mHealth apps identified from an overview of systematic reviews. NPJ Digit Med 2018;1(1):12, https://doi.org/10.1038/s41746-018-0021-9.
31. Brindal E, Hendrie G, Freyne J, Coombe M, Berkovsky S, Noakes M. Design and pilot results of a mobile phone weight-loss application for women starting a meal replacement programme. J Telemed Telecare 2013;19(3):166–74, https://doi.org/10.1177/1357633X13479702.
32. King AC, Hekler EB, Grieco LA, Winter SJ, Sheats JL, Buman MP, *et al*. Harnessing different motivational frames via Mobile phones to promote daily physical activity and reduce sedentary behavior in aging adults. Lucia A, ed. PLoS One 2013;8(4), https://doi.org/10.1371/journal.pone.0062613. e62613.
33. Cottrell MA, Galea OA, O'Leary SP, Hill AJ, Russell TG. Real-time telerehabilitation for the treatment of musculoskeletal conditions is effective and comparable to standard practice: a systematic review and meta-analysis. Clin Rehabil 2017;31(5): 625–38, https://doi.org/10.1177/0269215516645148.
34. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D. The impact of mHealth interventions: systematic review of systematic reviews. JMIR mHealth uHealth 2018;6(1):e23, https://doi.org/10.2196/mhealth.8873.
35. Fogg BJ. A behavior model for persuasive design. In: Proceedings of the 4th International Conference on Persuasive Technology - Persuasive '09. New York, New York, USA: ACM Press; 2009:1, https://doi.org/10.1145/1541948.1541999.
36. Pelle T, Bevers K, van der Palen J, van den Hoogen FHJ, van den Ende CHM. Development and evaluation of a tailored e-self-

management intervention (dr. Bart app) for knee and/or hip osteoarthritis: study protocol. BMC Muscoskel Disord 2019;20(1):398, https://doi.org/10.1186/s12891-019-2768-9.
37. de Groot IB, Reijman M, Terwee CB, Bierma-Zeinstra SMA, Favejee M, Roos EM, *et al*. Validation of the Dutch version of the hip disability and osteoarthritis outcome score. Osteoarthr Cartil 2007;15(1):104–9, https://doi.org/10.1016/j.joca.2006.06.014.
38. de Groot IB, Favejee MM, Reijman M, Verhaar JA, Terwee CB. The Dutch version of the knee injury and osteoarthritis outcome score: a validation study. Health Qual Life Outcome 2008;6(1):16, https://doi.org/10.1186/1477-7525-6-16.
39. EuroQol Group. EuroQol - a new facility for the measurement of health-related quality of life. Health Pol 1990;16(3):199–208, http://www.ncbi.nlm.nih.gov/pubmed/10109801.
40. Wagenmakers R, van den Akker-Scheek I, Groothoff JW, *et al*. Reliability and validity of the short questionnaire to assess health-enhancing physical activity (SQUASH) in patients after total hip arthroplasty. BMC Muscoskel Disord 2008;9(1):141, https://doi.org/10.1186/1471-2474-9-141.
41. Skolasky RL, Green AF, Scharfstein D, Boult C, Reider L, Wegener ST. Psychometric properties of the patient activation measure among multimorbid older adults. Health Serv Res 2011;46(2):457–78, https://doi.org/10.1111/j.1475-6773.2010.01210.x.
42. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception questionnaire. J Psychosom Res 2006;60(6):631–7, https://doi.org/10.1016/j.jpsychores.2005.10.020.
43. Cuperus N, Hoogeboom TJ, Kersten CC, den Broeder AA, Vlieland TPMV, van den Ende CHM. Randomized trial of the effectiveness of a non-pharmacological multidisciplinary face-to-face treatment program on daily function compared to a telephone-based treatment program in patients with generalized osteoarthritis. Osteoarthr Cartil 2015;23(8):1267–75, https://doi.org/10.1016/j.joca.2015.04.007.
44. Twisk J, de Boer M, de Vente W, Heymans M. Multiple imputation of missing values was not necessary before performing a longitudinal mixed-model analysis. J Clin Epidemiol 2013;66(9):1022–8, https://doi.org/10.1016/j.jclinepi.2013.03.017.
45. Pisters MF, Veenhof C, Schellevis FG, De Bakker DH, Dekker J. Long-term effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: a randomized controlled trial comparing two different physical therapy interventions. Osteoarthr Cartil 2010;18(8):1019–26, https://doi.org/10.1016/j.joca.2010.05.008.
46. Svege I, Nordsletten L, Fernandes L, Risberg MA. Exercise therapy may postpone total hip replacement surgery in patients with hip osteoarthritis: a long-term follow-up of a randomised trial. Ann Rheum Dis 2015;74(1):164–9, https://doi.org/10.1136/annrheumdis-2013-203628.
47. Kroon FP, van der Burg LR, Buchbinder R, Osborne RH, Johnston RV, Pitt V. Self-management education programmes for osteoarthritis. In: Buchbinder R, Ed. Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd; 2014:10–3, https://doi.org/10.1002/14651858.CD008963.pub2.
48. Claassen AAOM, Vliet Vlieland TPM, Busch VJJF, Schers HJ, van den Hoogen FHJ, van den Ende CHM. An electronic health tool to prepare for the first orthopedic consultation: use and usability study. JMIR Form Res 2019;3(4), https://doi.org/10.2196/13577. e13577.
49. Timmers T, Janssen L, Pronk Y, *et al*. Assessing the efficacy of an educational smartphone or tablet app with subdivided and interactive content to increase patients' medical knowledge: randomized controlled trial. JMIR mHealth uHealth 2018;6(12), https://doi.org/10.2196/10742. e10742.
50. Short CE, DeSmet A, Woods C, Williams SL, Maher C, Middelweerd A, *et al*. Measuring engagement in eHealth and mHealth behavior change interventions: viewpoint of methodologies. J Med Internet Res 2018;20(11):e292, https://doi.org/10.2196/jmir.9397.
51. Pham Q, Wiljer D, Cafazzo JA. Beyond the randomized controlled trial: a review of alternatives in mHealth clinical trial methods. JMIR mHealth uHealth 2016;4(3):e107, https://doi.org/10.2196/mhealth.5720.
52. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JEWC. Persuasive system design does matter: a systematic review of adherence to web-based interventions. J Med Internet Res 2012;14(6):1–24, https://doi.org/10.2196/jmir.2104.
53. Eysenbach G. The law of attrition. J Med Internet Res 2005;7(1):e11, https://doi.org/10.2196/jmir.7.1.e11.
54. Conaghan PG, Dickson J, Grant RL. Care and management of osteoarthritis in adults: summary of NICE guidance. BMJ 2008;336(7642):502–3, https://doi.org/10.1136/bmj.39490.608009.