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Original article

The *iCanCope* pain self-management application for adolescents with juvenile idiopathic arthritis: a pilot randomized controlled trial

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Abstract

Objectives. To evaluate the feasibility and preliminary effectiveness of *iCanCope with Pain* (*iCanCope*), a smartphone-based pain self-management program, in adolescents with JIA. *iCanCope* featured symptom tracking, goal-setting, pain coping skills and social support.

Methods. A two-arm pilot randomized controlled trial was used to evaluate the *iCanCope* app compared with a version with symptom tracking only. Primary (feasibility) outcomes were: participant accrual/attrition rates, success of app deployment, acceptability and adherence. Secondary (preliminary effectiveness) outcomes were: pain intensity, pain-related activity limitations and health-related quality of life. Outcomes were assessed at baseline and 8 weeks. Adherence was defined as the proportion of completed symptom reports: 'low' (≤24%); 'low-moderate' (25–49%); 'high-moderate' (50–75%); or 'high' (76–100%). Linear mixed models were applied for preliminary effectiveness analyses as per intention-to-treat.

Results. Adolescents ($N = 60$) were recruited from three paediatric rheumatology centres. Rates of accrual and attrition were 82 and 13%, respectively. Both apps were deployed with high success (over 85%) and were rated as highly acceptable. Adherence was similar for both groups, with most participants demonstrating moderate-to-high adherence. Both groups exhibited a clinically meaningful reduction in pain intensity (≥1 point) that did not statistically differ between groups. There were no significant changes in activity limitations or health-related quality of life.

Conclusion. The *iCanCope* pilot randomized controlled trial was feasible to implement in a paediatric rheumatology setting. Both apps were deployed successfully, with high acceptability, and were associated with moderate-to-high adherence. Preliminary reductions in pain intensity warrant a future trial to evaluate effectiveness of *iCanCope* in improving health outcomes in adolescents with JIA.

Trial registration. ClinicalTrials.gov identifier: NCT02764346.

Key words: juvenile idiopathic arthritis, pain, self-management, smartphone, pilot randomized controlled trial

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Rheumatology key messages

- The *iCanCope* pilot randomized controlled trial was feasibly implemented in a paediatric rheumatology setting.
- The *iCanCope* self-management app for JIA pain is highly acceptable and associated with moderate-to-high adherence.
- Clinically meaningful reductions in pain intensity warrant a larger *iCanCope* trial in adolescents with JIA.

Introduction

JIA is the most common paediatric rheumatic disease, affecting approximately 1 in 1000 children [1, 2]. The disease course may involve flares of increased disease activity or chronic joint inflammation, which can persist into adulthood [3, 4]. As described by a synthesis of qualitative studies, 'JIA can have a debilitating impact on children and adolescents. Patients must contend with unpredictable phases of incapacitating pain, stigmatization, and physical limitations' (p. 1403) [5].

Pain is reported as the most common and distressing symptom of JIA [2]. This pain is known to negatively affect all aspects of health-related quality of life (HRQL), including physical, emotional, social and role functioning [6]. Seventy-seven percent of North American paediatric rheumatologists acknowledge that youth with JIA continue to experience clinically significant pain despite adequate doses of anti-inflammatory and disease-modifying therapy [7]. Even a small reduction in pain is associated with improved HRQL in JIA patients [8].

Self-management can be defined as 'the individual's ability to manage the symptoms, treatment, physical, and psychological consequences and lifestyle changes inherent to living with a chronic illness' [9]. As children mature, they are expected to assume increasing responsibility for disease self-management [10]. However, adherence to JIA disease management is typically suboptimal [11–13]. Improved self-management early in the disease trajectory may help to improve health outcomes, including pain.

Digital technologies have shown promise in improving the accessibility and availability of education, psychosocial interventions and social support for adolescents with JIA [14, 15]. There is also preliminary evidence that self-management interventions can improve symptoms and health status in other childhood illnesses [16]. Smartphones are particularly well-suited to deliver self-management support to adolescents due to their widespread adoption, powerful technical capabilities and deep integration into daily routine [17, 18].

iCanCope with Pain (*iCanCope*) is a smartphone-based program that was developed to meet the need for an accessible, evidence-based self-management program for youth with persistent pain. *iCanCope* was created through a phased, user-centred design approach. In phase 1A, a qualitative needs assessment was completed in adolescents with persistent pain and health-care providers [19]. In phase 1B, a scoping review demonstrated that publicly available 'pain apps' lack: (i) comprehensive pain self-management content, (ii) engagement of patients, (iii) consultation with health-care professionals, (iv) a theoretical basis for content or design, and (v) none were focused on JIA [20]. In phase 2A, group design sessions were held with end users (adolescents with different types of persistent pain, including JIA), app designers and members of the research team. In phase 2B, a prototype app was designed by a team of professional designers and human factors specialists. The prototype then underwent iterative cycles of usability testing with a sample of 15 young people with persistent pain to ensure that it was easy to use and was perceived as valuable [21]. The final *iCanCope* intervention app (iOS/Android) includes features of symptom tracking, goal setting, library of disease education and pain coping strategies, and peer-based social support (supplementary Fig. S1, available at *Rheumatology* online). A symptom tracking-only version of *iCanCope* (iOS/Android) was also developed for use in this trial as an attention-control condition (see Study conditions).

This study was focussed on evaluating the feasibility and preliminary effectiveness of the *iCanCope* pain self-management program in adolescents with JIA.

The primary objective was to determine whether the *iCanCope* program could be feasibly implemented as planned. The specific feasibility outcomes were: participant accrual and attrition rates; success of app deployment; acceptability of the study conditions; and adherence of adolescents with JIA to daily symptom tracking on a smartphone app, with and without the presence of other self-management features.

The secondary objective was to determine whether use of *iCanCope* by adolescents with JIA aged 12–18 years leads to differences in pain intensity, pain-related activity limitations and HRQL after 8 weeks, compared with a symptom tracking condition.

The exploratory objective was to characterize how adolescents with JIA engage with the intervention and attention-control versions of the *iCanCope* app.

Methods

Trial design

A two-arm parallel group pilot randomized controlled trial design was used to compare the *iCanCope* smartphone intervention condition with a smartphone-based

control (symptom tracking) condition. The allocation ratio was 1:1. The trial is registered on ClinicalTrials.gov with the identifier NCT02764346. The study was approved by the locally responsible Research Ethics Boards at each of the participating institutions.

Participants

Adolescents were recruited in person from three Canadian paediatric rheumatology centres. Adolescents were eligible to participate if they were: (i) aged between 12 and 18 years, (ii) diagnosed with JIA as per their rheumatologist [22], (iii) able to speak and read English, (iv) experiencing average arthritis-related pain in the past week of >3 on a 0–10 numerical rating scale (NRS) as per self-report, (v) able to complete online outcome measures via home computer or tablet and (vi)able to have daily access to a smartphone (iPhone or Android). Adolescents were excluded if they: (i) were already enrolled in another JIA intervention study, and/or (ii) had major comorbid illnesses or cognitive impairments that could affect their ability to use and understand the *iCanCope* program as per their healthcare provider, and/or (iii) took part in a previous *iCanCope* study. Participants received gift cards (total value CAD$70) in recognition of their time and commitment to the study.

Study conditions

Participants were randomized to receive one of two possible study apps (see Table 1). The intervention condition was a version of the *iCanCope* app that included symptom tracking as well as other self-management features. The control condition was a version of *iCanCope* that included symptom tracking features only. This condition was designed to control for the potential effects on outcomes of time, attention from the research team (including app orientation and study communication) and smartphone-mediated symptom tracking during the study period.

Outcomes

Outcomes were completed at two different time-points: baseline (T_1; after consent, before randomization) and condition completion (8 weeks after randomization; T_2). They were completed online by participants through the Research Electronic Data Capture (REDCap) secure web-based system, hosted at The Hospital for Sick Children. Study coordinators contacted participants via telephone and e-mail to remind them to complete outcomes. All patient-reported outcome measures have evidence of validity and reliability for adolescents with arthritis.

Background outcomes

Participant characteristics were captured at baseline: sociodemographic variables, JIA diagnosis and disease duration. Disease activity was measured through a baseline Physician Global Assessment [25]. The Physician Global Assessment assesses current disease activity on a 0–10 NRS with the anchors of 'no activity' and 'maximum activity'.

Implementation outcomes

- Participant accrual and attrition rates were calculated based on data from coordinator tracking logs.
- Successful app deployment, defined as installing and logging into the assigned app, was calculated based on data from coordinator tracking logs.
- Acceptability of the assigned *iCanCope* app was measured using the Acceptability e-Scale [26]. This tool uses 5-point Likert scales where a higher score indicates higher acceptability. The range of possible acceptability scores was 8 to 40.
- Adherence was measured using the Analytics Platform for Evaluating Effective Engagement (APEEE) [27], a proprietary analytics software. APEEE was used to capture number of symptom Check-Ins completed and interaction with the History feature.

Preliminary effectiveness outcomes

- Pain intensity was measured using an 11-point NRS with the anchors of 0 ('no pain') and 10 ('most pain possible') [28]. This scale assesses usual level of pain in the past 7 days.
- Pain-related activity limitations was measured using the Child Activity Limitations Interview (CALI-21) [29]. The CALI-21 assesses functional impact of persistent pain. Respondents rate their level of difficulty with 21 different activities over the past 4 weeks because of pain. Each item is rated on a 5-point NRS ranging from 0 'not very difficult' to 4 'extremely difficult'. The range of possible CALI-21 scores was 0–80.
- HRQL was measured using the PedsQL 3.0 Arthritis Module [30]. This tool assesses problems with pain and hurt, daily activities, treatment, worry and communication over the past month. Items are rated to reflect problem frequency using 5-point Likert scales ranging from 'never' to 'almost always'. The range of possible HRQL scores was 0–100.

Exploratory outcomes

- App engagement was measured using APEEE [27]. Frequencies of symptom Check-In completion and interaction with the History feature were captured for both groups. Frequency of user interaction with Goals, Library and Community features were captured for intervention participants only.

Sample size

Hertzog recommends that pilot studies should include 20–30 participants per group to examine feasibility of a larger, fully powered trial [31]. We therefore planned to randomize 60 adolescents to one of the two study conditions.

Table 1 Feature overview of the *iCanCope* program for adolescents with JIA by study condition

iCanCope feature	Study condition	Description
Check-In	Both (i.e. attention-control and intervention)	Daily symptom tracker for pain intensity, pain interference, mood, physical activity, sleep quality and energy. Pain intensity was self-reported on a 0–10 numerical rating scale with the anchors 'no pain' and 'worst pain'. Other symptom categories were captured via individual 5-point Likert scale where a lower score indicated better function. Participants received daily push notifications to complete a Check-In at a time of their choice.
History	Both	Interactive calendar interface with filters for different parameters from the Check-In. Designed to allow users to view their historical symptom data and understand trends.
Pain Areas	Both	Selectable body map [23] to capture pain location (body part), pain quality (word descriptors) and pain triggers (word descriptors).
Inflammation Areas	Both	Selectable body map to capture areas of JIA inflammation.
Goals	Intervention only	Create and track personalized goals to improve JIA pain and function. Goals could be created within the categories of physical activity, sleep, social, mood and energy. Users could either write their own goal or customize pre-populated goals within each category. Goals were encouraged to adhere to the SMART framework [24]. Each goal was structured as a single sentence, such as: 'Wind down an hour before bed by journaling'. Users could view all of their active goals and mark goals as 'complete' when applicable. Specific goals were suggested to users based on their Check-In data as per an app algorithm. For instance, if a user was reporting poor mood, they would be pushed a mood-related goal to try.
Library	Intervention only	Comprised of approximately 100 articles. Each article was focussed on JIA disease education, pain coping strategies (e.g. yoga exercises, belly breathing), or disease self-management (e.g. strategies to remember to take JIA medications). Articles contained a mixture of text, illustrations, videos and audio-recordings. Each article was 300 words or less and written at a grade 6–7 reading level. Specific articles were pushed to users based on their Check-In data as per an app algorithm. For instance, if a user was reporting poor sleep, they would be pushed an article with advice for improving sleep.
Community	Intervention only	'Question of the week' style forum where users could post short answers to questions posed by the app. Questions were designed to build a positive, supportive community of app users. They were written in consultation with patient partners (young people with persistent pain) on the research team. Example questions: 'what helps you to fall asleep?'; 'what advice would you give your younger self?'; 'what motivates you to get moving?' Users could post responses that were visible to all app users or 'favourite' other people's posts. The community was monitored by the research team and users could also flag content that they found inappropriate, if needed. Users were identified within the community by nicknames only.

SMART: specific, measurable, achievable, realistic/relevant and timed.

Randomization and condition deployment

Randomization was centrally controlled, concealed and balanced by study centre (i.e. to control for centre-specific JIA education). A secure, web-based randomization service (www.randomize.net) was used for allocating participants to the study groups. Following randomization, participants were sent standardized instructions on how to download and access their assigned app on their personal smartphone. A research team member facilitated an app orientation with each participant over the telephone. During orientation (15–30 min), participants were guided through the app features and completed their first symptom Check-In.

Blinding

Adolescents were blinded to their assigned study group. Both groups received a version of the *iCanCope* app and equal attention from the study team. The statistician was blinded to group identification during the analysis.

Statistical methods

Data were analysed using STATA version 15.1 (Stata Statistical Software, StataCorp, College Station, TX, USA, 2017). Descriptive statistics were used to describe background characteristics of the sample.

Implementation outcomes
Accrual rates were calculated as follows: *n* consented/*n* approached; *n* randomized/*n* consented. Attrition was calculated as follows: *n* lost to follow-up/*n* randomized. Lost to follow-up was defined as a participant who was missing all outcome data after baseline. Thresholds for acceptable accrual (randomized/consented) and attrition rates were set at >70% and <20%, respectively, based on previous work [32]. The rate of successful app deployment was calculated for each study group as: *n* randomized/*n* logged into assigned app. Deployment success was classified as low (≤50%), moderate (51–80%) or high (81–100%). Descriptive statistics were used to summarize data on acceptability and engagement. As per author recommendations [26], sufficient acceptability was defined as 80% of the highest possible score on the Acceptability e-Scale (i.e. 32/40). Adherence was operationally defined [33] as the relative proportion of symptom Check-Ins that were completed over the 55-day study period: 'low adherence' (≤24%; <13 reports); 'low-moderate adherence' (25–49%; 14–27 reports); 'high-moderate adherence' (50–75%; 28–41 reports); or 'high adherence' (76–100%; 42–55 reports).

Preliminary effectiveness outcomes
As per an intent-to-treat approach, all participants were analysed according to the study arm to which they were randomized. A significance level of 0.05 was used for the preliminary effectiveness outcomes of pain intensity, pain-related activity limitations and HRQL. Linear mixed models, adjusting for baseline values, were used to assess the effects of the intervention on outcomes of interest. Given the exploratory nature of the pilot trial, no adjustments were made for multiple comparisons.

Exploratory outcomes
Descriptive statistics were used to summarize frequencies of app engagement across features.

Results

Participants

Recruitment was carried out between June 2017 and April 2019. The Consolidated Standards of Reporting Trials [34] (CONSORT) flow diagram detailing participant enrolment, allocation, follow-up and analysis is provided in Fig. 1. The randomized study sample was comprised of 60 adolescents. Characteristics of the adolescent sample, categorized by assigned study condition, are provided in Table 2. Almost all participants ($n = 56$; 93.3%) used a smartphone multiple times per day.

Primary outcomes: implementation

Accrual and attrition
Calculated rates of participant accrual and attrition were:

- 73 consented/129 approached (56.59%)
- 60 randomized/73 consented (82.19%)
- 8 lost to follow-up/60 randomized (13.3%)

Deployment of study conditions
The rates of successful app deployment for the intervention and attention-control conditions were: 25/29 (86%) and 31/31 (100%), respectively.

Acceptability of study conditions
Both study conditions surpassed the threshold for sufficient acceptability. The mean (S.D.) acceptability scores were 34.7 (S.D. 4.9) and 34.6 (S.D. 3.7) for intervention and attention-control participants, respectively.

A majority of intervention participants (57%) were willing to use their assigned app for longer than 8 weeks (i.e. the study period). The remainder of intervention participants were willing to use the app for: 4 weeks (4%) or 8 weeks (39%). Attention-control participants were willing to use their assigned app for: 4 weeks (3%), 6 weeks (7%), 8 weeks (48%) or longer than 8 weeks (41%).

Adherence to daily symptom tracking
The mean number of completed daily Check-Ins was 29.6 (S.D. 14.5) for intervention participants and 29.0 (S.D. 11.7) for attention-control participants. As per operational definitions of adherence, intervention participants who received the app ($n = 25$) were distributed as follows: low (3, 12%), low-moderate (8, 32%), high-moderate (9, 36%) and high (5, 20%). Attention-control participants who received the app ($n = 29$) were distributed as follows: low (3, 10%), low-moderate (10, 34.5%), high-moderate (10, 34.5%) and high (6, 21%). Fig. 2 displays the total number of participants who completed a Check-In as a function of time, categorized by study group.

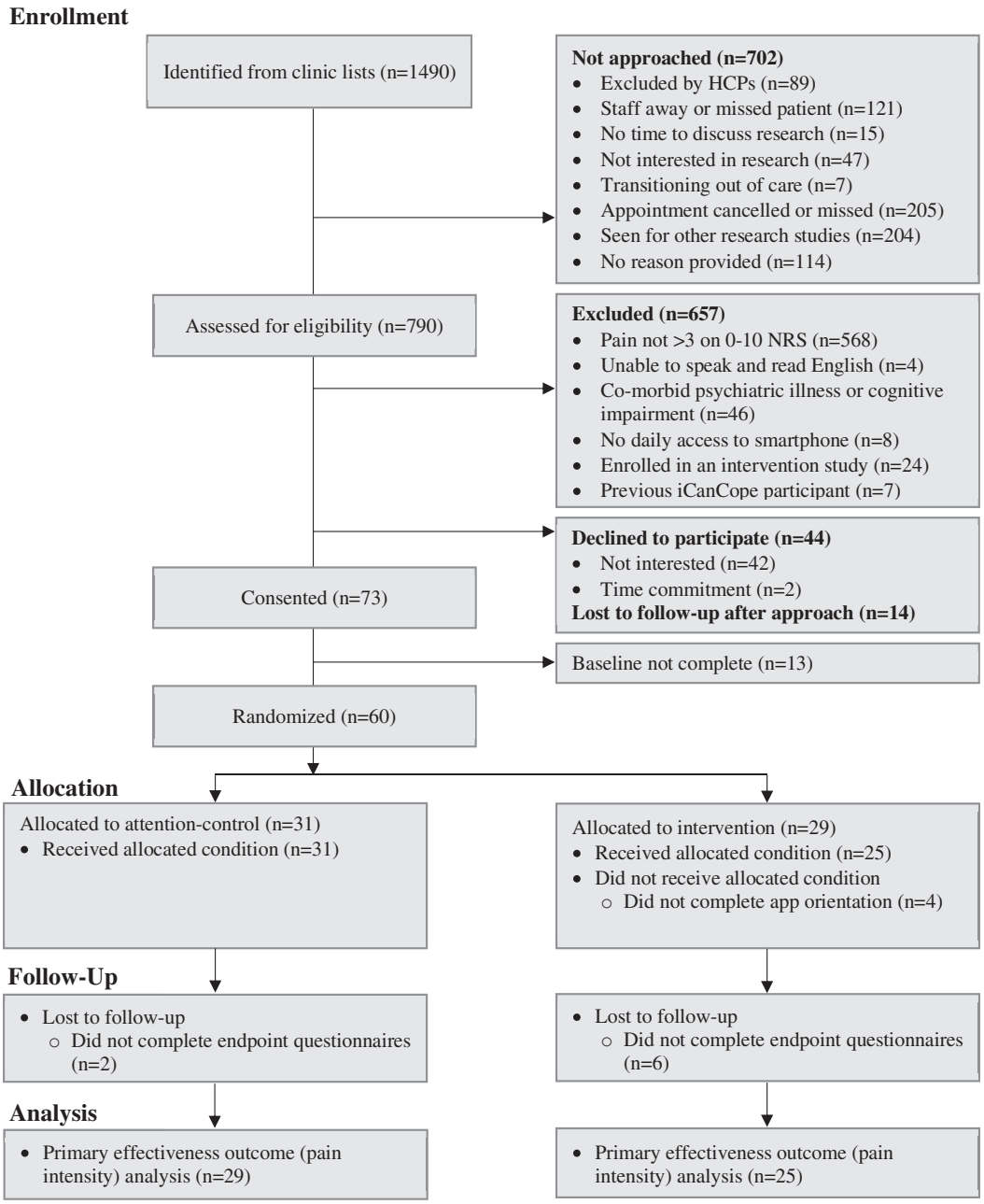
Overall, 16/25 (64%) intervention participants and 23/29 (79%) attention-control participants accessed the History function at least once during the 55-day study period. Supplementary Fig. S2, available at *Rheumatology* online, displays the breakdown of views for each symptom category within History according to study group. The app is designed such that when users open the History section, they are shown the pain intensity heat map by default. The total view count includes users who opened the History section multiple times in the same day or filtered between different symptoms within the same viewing session.

Secondary outcomes: preliminary effectiveness

Fig. 3 depicts the observed changes in pain intensity outcomes. Both groups exhibited improvements in pain intensity over time. There was a 1.73-point reduction for intervention participants and a 1.09-point reduction for attention-control participants. These changes in pain intensity did not statistically differ between groups ($P = 0.24$).

Supplementary Figs S3 and S4, available at *Rheumatology* online, depict changes in pain-related

FIG. 1 CONSORT diagram [33]



CONSORT: Consolidated Standards of Reporting Trials; HCP: healthcare provider; NRS: numerical rating scale.

activity limitations and health-related quality of life outcomes, respectively. There were no significant changes in pain-related activity limitations ($P = 0.650$) or HRQL ($P = 0.141$–0.885). See Supplementary Table S1, available at *Rheumatology* online, for the regression output for all preliminary effectiveness outcomes.

Exploratory outcome: engagement

Engagement with available app features among intervention and attention-control participants is summarized in Table 3.

Table 2 Adolescent demographic and disease characteristics

Characteristic	Overall ($N = 60$)	Intervention ($n = 29$)	Attention-control ($n = 31$)
Age in years, mean (S.D.)	15.0 (1.7)	14.9 (1.7)	15.1 (1.6)
Sex, *n* (%)			
Female	47 (78.3)	23 (79.3)	24 (77.4)
Male	13 (21.7)	6 (20.7)	7 (22.6)
Race, *n* (%)			
Aboriginal	2 (3.5)	1 (3.4)	1 (3.6)
Arab or West Asian	2 (3.5)	0 (0.0)	2 (7.1)
Black	1 (1.8)	1 (3.4)	0 (0.0)
Chinese	1 (1.8)	0 (0.0)	1 (3.6)
Filipino	1 (1.8)	1 (3.4)	0 (0.0)
Multi-racial	6 (10.5)	4 (13.8)	2 (7.1)
South Asian	3 (5.3)	2 (6.9)	1 (3.6)
South East Asian	1 (1.8)	0 (0.0)	1 (3.6)
White	40 (70.2)	20 (69.0)	20 (71.4)
JIA category, *n* (%)			
Systemic	3 (5.2)	1 (3.6)	2 (6.7)
Oligoarthritis	9 (15.5)	5 (17.9)	4 (13.3)
Oligoarthritis—extended	5 (8.6)	1 (3.6)	4 (13.3)
Polyarthritis (RF–)	14 (24.1)	9 (32.1)	5 (16.7)
Polyarthritis (RF+)	3 (5.2)	2 (7.1)	1 (3.3)
Psoriatic arthritis	7 (12.1)	3 (10.7)	4 (13.3)
Enthesitis-related arthritis	12 (20.7)	5 (17.9)	7 (23.3)
Undifferentiated	3 (5.2)	1 (3.6)	2 (6.7)
Other	2 (3.4)	1 (3.6)	1 (3.3)
Disease severity, *n* (%)			
Low (0–3 PGA)	36 (70.6)	17 (68.0)	19 (73.1)
Moderate-to-severe(4–10 PGA)	15 (29.4)	8 (32.0)	7 (26.9)
Duration of illness in years, mean (S.D.)	6.0 (5.1)	6.5 (5.4)	5.5 (4.8)

Missing from analyses: race, $n = 3$ (attention-control $n = 3$); JIA category, $n = 2$ (attention-control $n = 1$, intervention $n = 1$); disease severity, $n = 9$ (attention-control $n = 5$, intervention $n = 4$); duration of illness, $n = 5$ (attention-control $n = 4$, intervention $n = 1$). PGA: Physician Global Assessment [27].

Fig. 2 Proportion of participants who completed a Check-In as a function of time, by study group

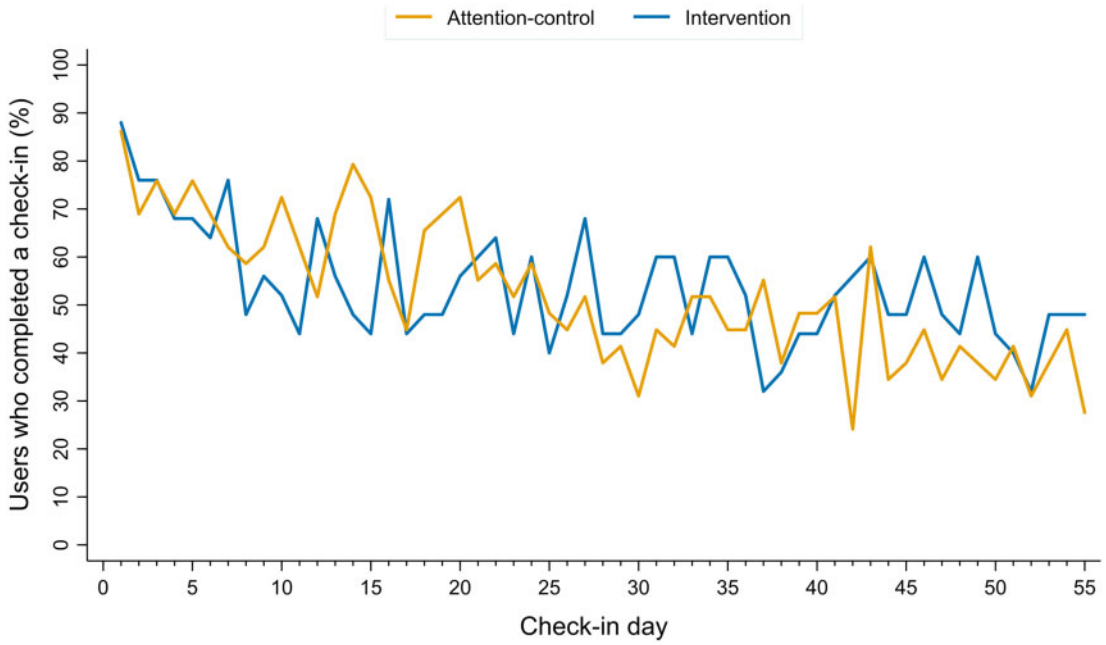
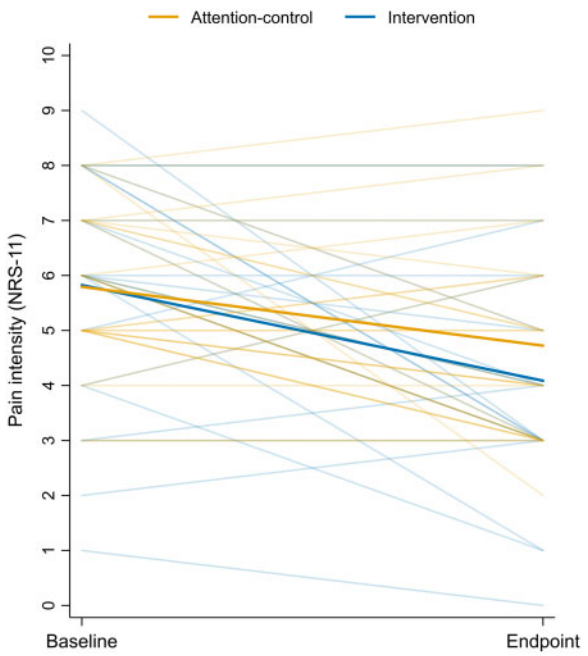


Fig. 3 Linear mixed models for pain intensity data



Lower scores indicate less pain. Thin lines represent raw individual participant scores at baseline and endpoint. Thicker lines show overall fitted values in each group based on the regression model.

Table 3 Engagement with available app features by study group

App feature	Intervention (n = 25), n (%)	Attention-control (n = 29), n (%)
Check-Ins	25 (100)	29 (100)
History	16 (64)	23 (79)
Pain areas	17 (59)	17 (59)
Inflammation Areas	13 (52)	14 (48)
Goals	11 (44)	Feature not available
Library	12 (48)	Feature not available
Community	10 (40)	Feature not available

Discussion

Main findings

This study sought to evaluate the feasibility and preliminary effectiveness of the *iCanCope* pain self-management program in adolescents with JIA. Our results indicate that the *iCanCope* trial is feasible to implement as planned. Across study sites, local research staff were able to randomize 82% of those consented and study attrition was <15%. Both study conditions were deployed with high success as per operational definitions and were rated as highly acceptable by participants. Participants displayed similar levels of adherence to the intervention and attention-control versions of the app, with a majority exhibiting moderate to high adherence. Pain intensity improved in both groups by 1.73 points (intervention) and 1.09 points (attention-control), respectively. These changes exceed the minimal clinically important difference for adolescents with persistent pain, which is >1 point on a 0–10 NRS [35]. There were no significant changes in pain-related activity limitations or HRQL. Exploratory analyses indicated that participants exhibited varying levels of engagement with available app features.

Comparison with previous work

A previous feasibility study was conducted to evaluate a version of the *iCanCope* app for adolescents with chronic pain [33]. In that study, $N = 60$ adolescents with chronic pain were randomized to use an intervention or attention-control version of *iCanCope* for 8 weeks. The content of the chronic pain app was similar to the JIA version, except that there was no body map for inflammation, and some library articles were disease specific. Results from the chronic pain feasibility study were similar to the present JIA study. Both versions of the chronic pain app were deployed with high success. Chronic pain participants displayed similar levels of adherence to the intervention and attention-control apps, with a majority exhibiting moderate to high adherence. Effectiveness of *iCanCope* in chronic pain-related health outcomes is being evaluated in an ongoing full-scale randomized controlled trial.

Engagement with self-management features

While participants in both groups exhibited similar adherence to Check-Ins, members of the attention-control group were somewhat more likely to view their symptom trends via the History feature. Conceivably, attention-control participants may have engaged more strongly with symptom tracking because it was the only feature available in their proffered app. Although intervention participants had access to additional self-management features (i.e. Goals, Library, Community), only 40–44% chose to engage with this additional app content. This study evaluated the first iteration (i.e. version 1) of *iCanCope*, which included some design elements intended to promote engagement across features. For example, an internal algorithm was used to push suggested content (i.e. Goals, Articles) to users based on their computed Check-In data. Given that fewer than half of intervention participants actually engaged with this content, the next iteration of *iCanCope* will implement strategies

intended to boost engagement. First, the app homepage will be redesigned to highlight daily messages and suggested content. Second, the app articles will be restructured to be shorter, use more playful language and incorporate more images of the app character rather than stock photos. Third, the History feature will be updated to support customizable graphs of symptom data over week and month views. Lastly, the content suggestion algorithm will be adjusted based on pilot data.

Study strengths

The *iCanCope* app for adolescents with JIA pain was developed through a phased, user-centred design approach that involved end-users in all stages. An app-based comparator was chosen to control for the potential effects of attention from the research team and provision of a study-issued symptom tracking app. Participant blinding was also strengthened by providing both groups with a version of the *iCanCope* app. Lastly, rigorous training of study personnel across the participating hospitals helped to ensure consistent protocol implementation across sites.

Study limitations

Given the lack of a third study arm, we cannot assess the effect of *iCanCope* relative to usual care alone [36]. Although the reported study attrition aligns with previous JIA studies [15, 37, 38], it nevertheless took 22 months to randomize 60 adolescents. The pace of technology change necessitates rapid methods of evaluation, otherwise risking app obsolescence by the time a trial is complete [39]. Our research group is presently exploring the open-source ResearchKit framework (Apple Inc.) as a means to expand *iCanCope* recruitment from paediatric hospitals to include remote community-based enrolment [40]. Theoretically, the remote screening, consenting and onboarding of trial participants through ResearchKit may enhance future enrolment rates.

Future work

In the present study, participants who received either version of the *iCanCope* app exhibited improvements in pain intensity that exceeded the threshold of clinical importance [35]. These preliminary reductions in pain intensity warrant a future larger trial to evaluate program effectiveness in improving JIA health outcomes. Further work is also needed to explore how symptom tracking alone may confer benefit to JIA patients. Conceivably, the acts of symptom tracking and viewing of historical trends may have prompted users to reflect on their behaviours and make adjustments in their daily life (e.g. prioritizing sleep). Future work will explore this possibility and also collect comparator data from a 'usual care' cohort. Innovative trial designs will be considered for a larger program evaluation, as they may be better suited to keep pace with the rate and scope of change in digital health [39]. Recently, the application of digital health analytics, defined as 'the discovery and communication of patterns in health data', has emerged as an efficient approach to evaluate digital health interventions [41]. Numerous evaluations have mined the rich log data generated by users engaging with these interventions and have successfully generated evidence of their impact on health outcomes [42]. In turn, the analytic models derived from these efforts have enhanced intervention effects through identifying the mediating behavioural mechanisms that motivate improved outcomes. In future work, our research group will explore data-driven study designs and methods that leverage the continuous stream of data generated by *iCanCope* to optimize effective app engagement and generate timely evidence of its impact on pain-related functional outcomes.

Conclusions

The *iCanCope* pilot randomized controlled trial was feasible to implement in a paediatric rheumatology setting. Both study apps were deployed successfully, acceptable and associated with moderate-to-high adherence in most adolescents with JIA pain. Preliminary reductions in pain intensity warrant a future trial to evaluate the effectiveness of *iCanCope* in improving health outcomes in adolescents with JIA.

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Supplementary data

Supplementary data are available at *Rheumatology* online.

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