A ResearchKit app to deliver paediatric electronic consent: Protocol of an observational study in adolescents with arthritis

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ResearchKit is an open-source software framework designed to streamline the process of screening and consenting participants into research studies. By digitizing traditionally analog processes, ResearchKit has potential to increase the reach, efficiency, and scalability of mobile health (mHealth) research. The model has been successfully applied in adult settings. However, to our knowledge, no group has sought to adapt ResearchKit for a paediatric research environment in Canada. The potential benefits for building paediatric mHealth apps compatible with remote eConsent are numerous: (1) access to studies can be broadened from small groups of children and families who live in close proximity to research sites to whole populations across geographical boundaries, (2) increased convenience for study participants because they can complete consent on their smartphone from their home, rather than in person or on paper, and (3) large-scale study enrollment can be conducted with fewer resources than traditional face-to-face methods. We describe the rationale and design of a proof-of-concept observational study focused on implementing remote eConsent in a Canadian paediatric population. A community-based sample of adolescents with arthritis will be remotely onboarded to use the iCanCope app for 8-weeks. Outcomes will focus on: (1) fidelity and acceptability of the eConsent process, (2) fidelity of the iCanCope app in terms of engagement and acceptability, (3) participant study experience including level of perceived support and acceptability of study tasks, and (4) clinical outcomes related to use of the iCanCope app over an 8-week period.

1. Introduction

1.1. ResearchKit: a framework to streamline and scale digital health trials

In recent years, numerous calls have been made to address the inherent challenges of rigorously evaluating mobile health (mHealth) interventions [1–3]. In March 2015, Apple Inc released ResearchKit, an open-source software framework that enables remote study screening and enrollment, including facilitation of informed consent. Historically, the use of in-person enrollment has hindered participant accrual and limited the scalability of clinical research [4]. By transforming the traditional face-to-face screening and consent process into a digital experience, ResearchKit has potential to increase the efficiency and scalability of mHealth research.

The potential benefits for building mHealth apps compatible with remote electronic consent (eConsent) are numerous [1]: access to studies can be broadened from small groups of people who live in close proximity to research sites to whole populations across geographical boundaries [2], increased convenience because participants can engage with the consent process on their smartphone, rather than in person or on paper, and [3] large-scale study enrollment can be conducted with fewer resources than traditional face-to-face methods.

Evidence of ResearchKit’s impact can already be seen through numerous adult research trials [5–15]. These studies offer convincing...
proof-of-concept for ResearchKit’s potential to transform adult clinical trial methodology.

1.2. Leveraging ResearchKit for a paediatric context

The ResearchKit platform includes features that could be particularly useful for enabling informed eConsent with children and adolescents. First, it provides a framework to digitally deliver all components of a traditional consent form within simple, digestible modules. Second, it provides opportunities to accommodate different learning styles by embedding explanatory videos and other interactive components to improve study comprehension [16]. Third, it can embed comprehension quizzes to ensure that potential participants understand the study design and required study tasks before deciding whether to take part.

To our knowledge, no group has sought to adapt ResearchKit for a paediatric research environment in Canada. To begin to address this gap, this study will serve as proof-of-concept for the first implementation of ResearchKit-enabled eConsent in a Canadian adolescent population.

1.3. Clinical condition of interest: juvenile idiopathic arthritis

Juvenile idiopathic arthritis (JIA) is the most frequent cause of chronic pain in youth and can negatively impact all aspects of health-related quality of life (HRQL). Many youth with JIA continue to have clinically significant pain despite medication [17,18]. Even a small reduction in JIA pain is associated with improved HRQL [17]. Adolescents with JIA are expected to assume increasing responsibility for managing their condition. While considerable progress is being made to improve access to chronic disease self-management by leveraging mHealth, there is currently no comprehensive or evidence-based mHealth app to support adolescents with JIA [19,20].

1.4. The iCanCope mHealth app for adolescents with arthritis

Our research is focused on development, evaluation, and implementation of iCanCope, the first smartphone-based pain self-management program tailored for adolescents with arthritis. iCanCope has been iteratively developed through a user-centred design approach [17]. The key features are [1]: symptom tracking [2]; goal-setting [3], self-management library, and [4] social support (see Fig. 1).

2. Methods

This study was reviewed and approved by the Research Ethics Board of The Hospital for Sick Children (REB #1000060822).

2.1. Study aim

Using the iCanCope pain self-management app for youth as a proof-of-concept for a paediatric context, this study will evaluate the use of remote eConsent in a Canadian paediatric population.

2.2. Research questions

1. eConsent (ResearchKit) Outcomes: Can remote eConsent via ResearchKit be successfully adapted for use in a paediatric arthritis population and deployed through the iCanCope app? Specifically: (1.1) can the process of participant screening, enrollment, and app deployment be automated with high fidelity to the protocol? (1.2) what are participant perceptions regarding acceptability and satisfaction with remote eConsent?

2. Intervention Outcomes: Can the iCanCope app be deployed and sustained with high fidelity? Specifically: (2.1) what are the levels of participant engagement with each app feature over the 8-week study period? (2.2) what are participant perceptions about the acceptability of the app?

3. Research Experience Outcomes: What are the perceptions of individuals with arthritis pain aged 12-18 years about participating in a remote and automated app-based study? Specifically: (3.1) how engaged do participants feel in the research study? (3.2) what are motivated participants to be part of the study? (3.3) how supported do participants feel by the research team? (3.4) how acceptable were the study tasks?

4. Clinical Outcomes: In individuals with arthritis pain aged 12-18 years, does use of a pain self-management app (iCanCope) over 8-weeks lead to differences in pain interference, pain intensity, pain coping, pain self-efficacy, self-management skills, and patient global impression of change between T1 (baseline) and T2 (immediately post-program; 8-weeks)?

2.3. Trial design and setting

A pragmatic observational study with convenience, community-based recruitment will be conducted. Adolescents with arthritis will be remotely recruited and onboarded into the study. They will use the iCanCope app for a period of 8-weeks and complete electronic study surveys at baseline (T1) and T2 (immediately post-program). The study will be based at The Hospital for Sick Children (SickKids) in Toronto, which is the largest paediatric hospital in Canada.

Fig. 1. Screenshots of the iCanCope pain self-management app. The app has been developed natively (iOS, Android) through a collaboration between the Centre for Global eHealth Innovation (University Health Network) and The Hospital for Sick Children in Toronto, Canada.
2.4. Participant identification and recruitment

A mixture of approaches and strategies will be used to identify and recruit study participants from the community. We will leverage the network of Cassie and Friends (study funder) to reach adolescents with JIA who may be interested in the study. Cassie and Friends is a Canadian charitable organization focused on supporting children and families affected by paediatric arthritis (https://cassieandfriends.ca). As of 2020, their network includes approximately 250 children with rheumatic disease, approximately 125 of whom are aged 11 and older.

Printed materials will be distributed at Cassie and Friends in-person events, targeted emails will be sent to organization members, advertisements will be posted on the organizational website, and curated social media will be targeted (e.g. organization’s Facebook page, Twitter feed, Instagram feed). All marketing materials were co-designed with Cassie and Friends and reviewed by the Public Affairs Department and Research Ethics Board of SickKids Hospital.

The study marketing materials contain instructions on how to download the iCanCope app and access the study eligibility screening process. Marketing materials will be playfully themed to recruit ‘citizen scientists’ into the research study. As per this theme, adolescents will be positioned as investigators in the study and be invited to examine what influences their arthritis pain. This theme is intended to empower youth with arthritis to become engaged in research. See Fig. A.1 for an example of the study marketing materials.

2.5. Study enrollment

Individuals will be able to self-enroll into the study by independently accessing the ResearchKit interface. After downloading the iCanCope app onto their personal device, they will be prompted to enter a study access code. This code will be provided on study marketing materials. After successfully entering the access code, the individual will be provided with a brief summary of the research study. They will then be shown an interactive screening survey to assess their eligibility for the study (Table 1). After completing the screening survey, the individual will either be directed to the consent materials or be notified that they are ineligible for the study (see Fig. 2 for eligibility output screens).

Over a 12-month period, our research team collaborated closely with the SickKids Research Ethics Board to determine how the standard paediatric research consent form could be adapted for ResearchKit delivery. The adaptation process focused on (1): distilling the content to its most important units [2], simplifying the language for 12-18 year olds to review independently [3], incorporating engaging components (e.g. graphics), and [4] adhering to ethical regulations at the institutional and national level.

In terms of content, our goals were to: (i) distill the paper consent (~5–10 single-spaced pages) into discrete modules (e.g. “Privacy,” “Time Commitment”), and (ii) display each module on a single ResearchKit screen. As shown in Fig. 3, each ResearchKit module screen includes a title (e.g. “Time Commitment”), representative graphic, paragraph of content, and a link to secondary page where they can learn more about the given topic. In discussion with the Research Ethics Board, it was agreed that all information that was essential for prospective participants to understand must appear within the paragraph on the primary module screen. Information that was considered supplementary could appear on the secondary “learn more” page, which is optional for the adolescents to view. By leveraging this tiered design, we aimed to streamline the eConsent content while providing adolescents with enough information to make an informed choice regarding study participation. A summary of the eConsent modules for this study is provided in Table 2.

2.6. Intervention

Following eConsent, participants will be given access to the iCanCope app. It has 4 main features [1]: symptom self-monitoring through a daily diary of pain, sleep, mood, physical activity, energy, and activity limitations data [2]; customizable goal setting related to improving pain and functioning [3]; personalized library of self-management content; and [4] peer-based social support through interaction with other app users. Participants will be encouraged to use the app (via automated push alerts) at least once per day over the 8-week period.

2.7. Study surveys

The Research Electronic Data Capture (REDCap) secure web-based survey platform will be used to deliver study surveys in a user-friendly format. Links to the surveys will be embedded in emails sent to participants at the pre-and post-study periods (i.e. T1 and T2). Details of the study surveys are outlined in Table 3.

| Table 1 | Eligibility screening process. |
|---------|-------------------------------|
| #       | Inclusion Criteria | Validation Method | Corresponding ResearchKit Survey Item |
| L.1     | Aged 12-18 years       | Self-report        | Are you between 12-18 years old? |
| L.2     | Diagnosed with arthritis| Self-report      | Has a doctor told you that you have juvenile arthritis? |
| L.3     | Experiences arthritis-related pain, stiffness, or swelling | Self-report | Do you ever feel pain, stiffness, or swelling in your joints? |
| L.4     | Resides in Canada      | App can only be downloaded from the Canadian App Store. Additionally, geolocation of device IPs will be used to confirm location. | N/A |
| L.5     | Able to speak and read English | Infer from ability to understand screening questions, consent form, and knowledge quiz. Note that it will not be possible to rule out possibility that a different person helped them to complete these steps. | N/A |
| L.6     | Daily access to an iCanCope-compatible mobile device (iPhone, iPod) with access to the Internet (data plan or Wi-Fi) | Individual will only be able to download and open the app on a compatible smartphone. Note that it will not be possible to independently confirm whether the individual has daily access to this device. | Is this your personal iPhone or iPod (so not your parent’s, sibling’s or friend’s device)? Do you use this iPhone or iPod every day? |
| L.7     | Cognitive capacity to independently provide informed consent | Infer from ability to understand screening questions, consent form, and knowledge quiz. Note that we will not be able to rule out possibility that a different person helped them to complete these steps. | N/A |
| E.1     | Participant in another iCanCope study (currently enrolled or completed). | Self-report as well as cross reference with hospital records of existing iCanCope participants. | Are you currently enrolled in another iCanCope study? |

app. It has 4 main features [1]: symptom self-monitoring through a daily diary of pain, sleep, mood, physical activity, energy, and activity limitations data [2]; customizable goal setting related to improving pain and functioning [3]; personalized library of self-management content; and [4] peer-based social support through interaction with other app users. Participants will be encouraged to use the app (via automated push alerts) at least once per day over the 8-week period.
2.8. Sample size

A community-based sample of adolescents with arthritis will be recruited from across Canada. Given that Cassie and Friends currently has a marketing presence in British Columbia, Alberta, and Ontario, we anticipate that most participants will be recruited from these provinces. We will aim to recruit a minimum of 50 participants to evaluate proof-of-concept but will attempt to recruit as many participants as possible within the study timeframe. This sample size was determined based on the recruitment pool available from the Cassie and Friends network.

2.9. Study compensation

Participants will not receive monetary compensation to be part of the study. The amount of cellular data used by the iCanCope app is negligible (~100 kB) so participants will not incur overage charges as part of the study. They will receive a letter indicating the completion of community service hours and a diploma related to their ‘citizen scientist’ role in the project. The absence of monetary compensation will help to determine the scalability of this research and hopefully dissuade members of the public from enrolling in the study if they are not adolescents with arthritis.

2.10. Data analysis

Data analyses will be performed using SAS v9.3. Distributions of outcome variables at each time point (and on difference scores between time points) will be examined first with summary statistics and graphical tools. For outcome variables with highly skewed distributions, we will either apply transformation or non-parametric test procedures as appropriate.

2.10.1. Analytic approach for research question 1

To determine whether the process of participant screening, enrolment, and app deployment can be automated with high fidelity, coordinator study logs will be examined. “High fidelity” will be defined as minimal technical difficulties encountered during the process of

| Table 2 | eConsent Modules for the iCanCope Study. |
|---------|-----------------------------------------|
| Module | Description |
| Welcome | Introduction to the study. |
| Pay Attention | Advise reader that there is a quiz at the end of the eConsent process. |
| Privacy | Explain measures taken to ensure privacy of participants. |
| Time | Outline time commitment involved in the study activities. |
| Surveys | Describe purpose, content, and number of study surveys. |
| Benefits | Outline potential study benefits. |
| Risk | Outline potential study risks. |
| Care | Advise that the study is not part of medical care. |
| Leaving the Study | Explain voluntary nature of the study and how to withdraw. |
| Rewards | Outline study reimbursement. |
| Questions | Provide contact information and availability of the research staff. |
| Comprehension | Multiple-choice quiz to confirm understanding of study. |
| Quiz | Display full consent form with “agree” and “disagree” buttons for adolescent to select. |
| Signature | Capture name and e-signature (time and date stamped). |

Fig. 2. Possible outputs of eligibility screening survey.

Fig. 3. Examples of ResearchKit eConsent module screens.
screening, enrolling, and deploying the app for a majority of participants. Participant perceptions regarding remote eConsent will be explored by summarizing responses on the Acceptability and Satisfaction Questionnaire using descriptive statistics.

### 2.10.2. Analytic approach for research question 2

Descriptive statistics will be used to explore levels of individual and aggregate participant engagement with each app feature (i.e. check-ins, goals, library, community) over the 8-week study period. Engagement will be defined as described in Table 4. Participant perceptions about acceptability of the app will be explored via responses on the Acceptability e-Scale. A mean score of greater than 3 on any item indicates item acceptability and a mean score of 4 or greater indicates high acceptability.

#### 2.10.3. Analytic approach for research question 3

Descriptive statistics will be used to explore individual perceptions about participating in a remote and automated app-based study based on Exit Survey responses.

#### 2.10.4. Analytic approach for research question 4

Analyses will be conducted using an intent-to-treat approach. If assumptions for parametric statistics are met, linear mixed models will be used to test intervention effects on pain interference, pain intensity, pain coping, pain self-efficacy, self-management skills, and PGIC outcomes with post-program measures compared between groups and baseline scores as covariates. Additionally, patient characteristics (e.g., gender and age) will be controlled for in the multivariable models.

### 2.11. Data security and storage

All data will be stored on the PHIPPA-compliant servers managed by the Centre for Global eHealth Innovation at University Health Network (Toronto, Ontario).

### 3. Discussion

#### 3.1. Study limitations

By design, ResearchKit studies are open to the public (i.e. any person with a smartphone can theoretically enroll). Due to resource limitations, we will be unable to independently verify that individuals who enroll are in fact young people who live with arthritis and are the same individuals who complete the study questionnaires (e.g. rather than their parents). We have mitigated risks to data integrity by Ref. [1]: not offering a monetary incentive for participation [2], disseminating our recruitment materials (containing the study access code) exclusively through Cassie and Friends marketing channels, and [3] embedding a robust enrolment process (e.g. eligibility quiz, e-mail verification, passcode creation) into our ResearchKit consent flow to deter against inappropriate study enrolment. This trial presents a minimal risk to participants due to the questionnaire structure of the study. Currently ResearchKit is only available for Apple devices, which means that only iPhones or iPods can be used in this study. If the eConsent process is found to be feasible using ResearchKit, then we will pursue future work to adapt the eConsent process for Android devices using ResearchStack.

Lastly, this study focuses on adolescents with the capacity to provide informed consent. If successful, lessons from this proof-of-concept study could be applied in future work to explore adapting ResearchKit for scenarios requiring research assent.

#### 3.2. Significance

Through the inaugural use of remote eConsent in a Canadian pediatric population, we believe our approach will be rapid, responsive,

### Table 3

| Outcome | Method of Assessment | Timing |
|---------|----------------------|--------|
| Research Question 1: eConsent Outcomes | | |
| Fidelity of automated participant screening, enrollment, and app deployment | Investigator-developed survey will assess participant perceptions regarding the eConsent process. | T1 |
| Participant acceptability and satisfaction with remote eConsent | Engagement with each feature will be tracked using the Analytics Platform to Evaluate Effective Engagement (APIEE) platform [21]. | |
| Research Question 2: Intervention-related Outcomes | | |
| Fidelity of iCanCope app deployment and onboarding process | Engagement with each feature will be tracked using the Analytics Platform to Evaluate Effective Engagement (APIEE) platform [21]. | |
| Engagement with iCanCope app | | |
| Research Question 3: Study Experience Outcomes | Investigator-developed survey to assess participant motivation for completing study, experience, engagement with study, and desired future use of iCanCope. | T2 |
| Research Question 4: Clinical Outcomes | | |
| Pain interference | PROMIS Pediatric Pain Interference Short Form [22] is an 8-item scale that assesses pain interference over the previous 7 days. Domains assessed are sleep, mood, schoolwork, concentration, physical function, and ability to have fun. | T1, T2 |
| Pain intensity and frequency | Pain intensity measured on the app daily check-in via 11-point numerical rating scale. Pain frequency is number of pain-days occurring during each 7-day measurement period. | Daily during study period |
| Pain coping | The Short-Form Pain Coping Questionnaire [23] is a measure of pain coping strategies in paediatric populations. Respondents indicate on a 5-point scale how often they use a given type of coping strategy from among 8 different categories. | T1, T2 |
| Pain self-efficacy | The Pain Self-Efficacy Questionnaire [24] (10 items) assesses confidence to engage in different tasks despite pain. | T1, T2 |
| Patient global impression of change | Patient Global Impression of Change (PGIC) (1 item) will assess participant impression of change in activity limitations, symptoms, emotions, and overall quality of life related to their painful condition. | T1, T2 |

### Table 4

| Categories of user-level app engagement. |
|-----------------------------------------|
| iCanCope feature | Low engagement | Moderate engagement | High engagement |
|------------------|----------------|---------------------|-----------------|
| Check-In | <25% of possible check-ins completed over 56 days (i.e. <14 reports) | 25-75% of possible check-ins completed over 56 days (i.e. 14-41 reports) | >75% of possible check-ins completed over 56 days (i.e. ≥42 reports) |
| Goals | No goals completed | To be defined based on usage data | To be defined based on usage data |
| Community | No interaction (posts, likes) | To be defined based on usage data | To be defined based on usage data |
and relevant in evaluating an mHealth app for youth with arthritis. By alleviating access barriers to study participation through remote automated recruitment and consent, the patient experience of participating in research is prioritized. Despite the increasingly pressing need to produce research findings that can keep pace with innovations in health technology, current evaluation practices in mHealth evaluation are still slow and cumbersome [25]. We believe that initiating this shift in both study design and methods for research on pediatric JIA mHealth interventions could have a significant impact on shortening the translation of research into practice, ultimately resulting in a future where youth with arthritis can have timely access to an effective and evidence-based intervention to support disease self-management.

The challenges associated with obtaining consent from adolescents through ResearchKit are significant yet must be addressed to advance and accelerate child health research. The iCanCope project is ideally positioned to begin to directly address these gaps in knowledge. This proof-of-concept study represents a unique opportunity to work with partners from paediatric research ethics to generate templates and guidelines for adapting ResearchKit for use in paediatric studies. Through this study, we will generate evidence and accumulate experience that can inform future policies to guide the use of eConsent across paediatric research settings.

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Declaration of competing interest

The authors have no competing interests to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2020.100525.

References

[1] Q. Pham, D. Wiljer, J.A. Cafazzo, Beyond the randomized controlled trial: a review of alternatives in mHealth clinical trial methods, JMIR MHealth UHealth 4 (3) (2016 Sep 9) e107.
[2] S. Michie, L. Yardley, R. West, K. Patrick, F. Greaves, Developing and evaluating digital interventions to promote behavior change in health and health care: recommendations resulting from an international workshop, J. Med. Internet Res. 19 (6) (2017) e232.
[3] S. Kumar, W.J. Nilzen, A. Abernethy, A. Atienza, K. Patrick, M. Pavel, et al., Mobile health technology evaluation: the mHealth evidence workshop, Am. J. Prev. Med. 45 (2) (2013) 228–236.
[4] B. Carlisle, J. Kimmelman, T. Ramnay, N. MacKinnon, Unsuccessful trial accrual and human subjects protections: an empirical analysis of recently closed trials, Clin Trials Lond Engl 12 (1) (2015 Feb) 77–83.
[5] V. Touraine, List of All ResearchKit Apps [Internet]. Shazino, 2016 [cited 2019 Jul 18]. Available from: http://blog.shazino.com/articles/science/researchkit-list-apps.
[6] Y.-F.Y. Chan, P. Wang, L. Rogers, N. Tignor, M. Zweig, S.G. Hershman, et al., The Asthma Mobile Health Study, a large-scale clinical observational study using ResearchKit, Nat. Biotechnol. 35 (4) (2017 Apr) 354–362.
[7] M. Crouthamel, E. Quattrocchi, S. Watts, S. Wang, P. Berry, L. Garcia-Gancedo, et al., Using a ResearchKit smartphone app to collect rheumatoid arthritis symptoms from real-world participants: feasibility study, JMIR MHealth UHealth 6 (9) (2018 Sep 13) e177.
[8] S. Deering, M.M. Grade, J.K. Uppal, L. Foschini, J.L. Juusola, A.M. Amdur, et al., Accelerating research with technology: rapid recruitment for a large-scale web-based sleep study, JMIR Res Protoc 8 (1) (2019), e10974.
[9] M.V. McConnell, A. Shcherbina, A. Pavlovic, J.R. Homburger, R.L. Goldfeder, D. Waggot, et al., Feasibility of obtaining measures of lifestyle from a smartphone app: the MyHeart counts cardiovascular health study, JAMA Cardiol 2 (1) (2017 Jan 1) 67–76.
[10] T. Inomata, M. Nakamura, M. Iwagami, T. Shiang, Y. Yoshimura, K. Fujimoto, et al., Risk factors for severe dry eye disease: crowdsourced research using DryEyeRhythm, Ophthalmolgy 126 (5) (2019 May 1) 766–768.
[11] D.E. Webster, C. Suver, M. Doerr, E. Mounts, L. Domenico, T. Petrie, et al., The Mole Mapper Study, mobile phone skin imaging and melanoma risk data collected using ResearchKit, Sci Data 4 (2017 Feb 14) 170005.
[12] S. Yamaguchi, K. Waki, Y. Nannya, M. Nakagaki, K. Ohe, Usage patterns of GlucoNote, a self-management smartphone app, based on ResearchKit for patients with type 2 diabetes and prediabetes, JMIR MHealth UHealth 7 (4) (2019), e13204.
[13] M. Zens, P. Woias, N.P. Suedkamp, P. Niemeyer, ‘Back on track’: a mobile app observational study using apple’S ResearchKit framework, JMIR MHealth UHealth 5 (2) (2017) e25.
[14] J.M. Radin, S.R. Steinhubl, A.I. Su, H. Bhargava, B. Greenberg, B.M. Bot, et al., The healthy pregnancy research program: transforming pregnancy research through a ResearchKit app, Npj Digit Med 1 (2018 Sep 5). UNSP 45.
[15] B.M. Bot, C. Suver, E.C. Neto, M. Kellen, A. Klein, C. Bare, et al., The mPower study, Parkinson disease mobile data collected using ResearchKit, Sci Data 3 (2016 Mar 3) 16011.
[16] E.W. Hall, T.H. Sanchez, A.D. Stein, R. Stephenson, M. Zlotorzynska, R.C. Sineath, et al., Use of videos improves informed consent comprehension in web-based surveys among internet-using men who have sex with men: a randomized controlled trial, J. Med. Internet Res. 19 (3) (2017), e1116.
[17] Y. Kimura, G.A. Walco, E. Sugarman, P.M. Conte, L.E. Schanberg, Self-reported pain item bank, J. Pain 11 (11) (2010 Nov) 1109.
[18] M.H. Bromberg, M. Connelly, K.K. Anthony, K.M. Gil, L.E. Schanberg, Self-reported pain and disease symptoms persist in juvenile idiopathic arthritis despite treatment advances: an electronic diary study, Arthritis Rheum. 66 (2) (2014) 462–469.
[19] C. Laloo, L.A. Jibb, J. Rivera, A. Agarwal, J.N. Stinson, ’There’s a pain app for that’: review of patient-targeted smartphone applications for pain management, Clin. J. Pain 31 (6) (2015) 557–563.
[20] C. Laloo, U. Shah, K.A. Birnie, C. Davies-Chalmers, J. Rivera, J. Stinson, et al., Commercially available smartphone apps to support postoperative pain self-management: scoping review, JMIR MHealth UHealth 5 (10) (2017) e162.
[21] Q. Pham, G. Graham, C. Laloo, P.P. Morita, E. Seto, J.N. Stinson, et al., An analytics platform to evaluate effective engagement with pediatric mobile health apps: design, development, and formative evaluation, JMIR MHealth UHealth 6 (12) (2018 Dec 21) e11407.
[22] J.W. Varm, B.D. Snuck, D. Thissen, E.M. Dewitt, D.E. Irwin, J.S. Lai, et al., PROMIS pediatric pain interference scale: an item response theory analysis of the pediatric pain item bank, J. Pain 11 (11) (2010 Nov) 1109–1119.
[23] G.J. Reid, C.A. Gilbert, P.J. McGrath, The pain coping questionnaire: preliminary validation, Pain 76 (1–2) (1998 May) 83–96.
[24] M.K. Nicholas, The pain self-efficacy questionnaire: taking pain into account, Eur. J. Pain 11 (2) (2007 Feb) 153–163.
[25] W.T. Riley, R.E. Glasgow, L. Etheredge, A.P. Abernethy, Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise, Clin. Transl. Med. 2 (1) (2013 May 10) 10.