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## LENDING AN EAR: IPEER2PEER PLUS TEENS TAKING CHARGE ONLINE SELF-MANAGEMENT TO EMPOWER CHILDREN WITH ARTHRITIS. PROTOCOL FOR A PILOT RCT.

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Manuscripts

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3 **LENDING AN EAR: IPEER2PEER PLUS TEENS TAKING CHARGE ONLINE**  
4 **SELF-MANAGEMENT TO EMPOWER CHILDREN WITH ARTHRITIS.**  
5 **PROTOCOL FOR A PILOT RCT.**  
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## Abstract

### Introduction:

Juvenile Idiopathic Arthritis (JIA) negatively affects adolescents' everyday activities. To address the need for innovative, effective, convenient, low-cost psychosocial self-management programmes, we developed an Irish version of Canadian Teens Taking Charge (TTC): and integrated it with skype-based peer support iPeer2Peer (iP2P).

Objectives:

- To evaluate feasibility and preliminary outcome impact (effectiveness) of an integrated iP2P and Irish TTC, via 3- arm (treatment as usual, TTC and iP2P-TTC) pilot RCT.
- To ensure the active involvement of adolescents with JIA throughout the study by the creation and support of a Young Person Advisory Panel (YPAP).

### Methods and analysis:

Single-blinded (outcome assessment), 3-arm pilot RCT, using on-line questionnaires. Assessments at baseline (T1), after intervention (T2), and 3 months post-intervention (T3). Primary outcomes on feasibility: comparisons of TTC and iP2P-TTC on fidelity, acceptability and satisfaction, engagement, and degrees of tailoring. Secondary outcomes: self-management and self-efficacy and a range of health-related quality of life factors, pain indicators, and costs. In addition, participants from the intervention groups will be invited to share their perspectives on the whole process in semi-structured interviews. Quantitative data will be analysed using SPSS version 21. Qualitative data will be audio-taped, transcribed and analysed using qualitative content analysis.

Ethical approval: Research Ethics Committees - National University of Ireland, Galway and Our Lady's Children's Hospital (OLCH), Crumlin, Dublin.

Dissemination: via journal articles, conference presentations, co-delivered by key stakeholders when possible, launch of accessible, effective and sustainable Internet self-management and peer support for Irish adolescents with JIA.

### Article Summary - Strengths and limitations

- This study follows from an in-depth qualitative exploration of the need and desire among stakeholders for an on-line support programme.

- The needs analysis offered suggestions on how to adapt the Canadian programme and these changes have been achieved.
- Canadian TTC is known to improve the lives of teens with JIA and their families, this study builds on that success by adding extra elements of tailoring and sustainability with the iP2P peer mentoring.
- Sustainability of the integrated programme, if found to be effective, is ensured due to: on-going collaboration with all stakeholders; AI taking over the peer mentoring element of the intervention, with on-going training and support for mentors, and; it being updated biannually by About Kids Health in Toronto.
- Recruitment of sufficient teens and their families for the RCT may be difficult, hence active involvement of all the stakeholder and the YPAP will be crucial to reach our target sample size.

## Introduction

JIA is the most common childhood rheumatic disease. In Ireland 1,200 children live with JIA, with over 100 children newly diagnosed annually,<sup>1</sup> according to Arthritis Ireland (AI). Children and adolescents commonly experience a myriad of physical and emotional symptoms that restrict physical and social interactions and negatively impact their health-related quality of life (HRQL).<sup>2,3</sup> There is no cure, the disease course can be unpredictable, and HRQL deteriorates with increased disease severity, active joint counts, pain, and degree of disability.<sup>2,3</sup> The Irish rheumatologist to patient ratio for children with arthritis is second lowest in Europe, with waiting lists of up to 2 years; access to psychological support is equally limited. In addition, transition to adult services is scheduled by age 16 years. So, although cognitive-behavioural therapy (CBT) interventions can lead to improvement in pain and health-related quality of life (HRQL),<sup>4</sup> most young people with JIA in Ireland will not receive these interventions. Hence, the need for supports to develop self-management skills for adolescents with JIA. Using the internet is a possible solution to address the gap between need, availability and access to effective treatments. Online interventions are scalable and accessible in the moment, 24 hours a day, and do not need therapist involvement.

Prior to this study, our Canadian colleagues had evaluated the two programmes in the present study separately. Stinson and colleagues developed and tested the usability, feasibility and effectiveness of Teens Taking Charge (TTC), an online self-management programme consisting of 12 modules for teens and 2 for parents, with telephone support from a health

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3 coach (trained, adult non-HCP without arthritis) for Canadian adolescents with JIA.<sup>3,5,6</sup>  
4 Significant improvements were found in disease-related knowledge, decreased pain and  
5 increased exercise adherence.<sup>6</sup> Peer support by another person with similar chronic illness is  
6 associated with improved health outcomes.<sup>7-10</sup> iPeer2Peer (iP2P), an online peer mentoring  
7 programme, was evaluated with adolescents with chronic pain, and found to improve  
8 acceptability of self-management and peer support treatments.<sup>11</sup> Although positively evaluated  
9 separately working with teens with JIA the two programmes have not be combined before.

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Localising available and effective programmes which meet the specific needs of patients is an  
important development strategy for facilitating timely availability of evidence-based  
programmes.<sup>12</sup> Hence we conducted an Irish qualitative needs assessment working with  
members (teens and parents) of two patient organisations: Arthritis Ireland (AI) and Irish  
Children's Arthritis Network (iCAN); health care professionals from Our Lady's Children's  
Hospital (OLCH) Crumlin and other paediatric units. The interviews explored stakeholder  
perspectives on:

- Impact of JIA on adolescents and families
- Current Irish service provision
- The value and usability of Canadian "TTC: Managing Arthritis Online" and iP2P programmes

Lack of access to health services was the main concern of all stakeholders, especially non-  
availability of local multidisciplinary rheumatology teams. There was consensus that TTC  
would be a useful resource for families and HCP once TTC information was tailored to the  
Irish context and specific needs of each patient, and facilitated through peer mentoring.<sup>13</sup>

These views taken together, underpin the critical need for accessible and effective interventions  
to assist Irish adolescents with JIA to find effective ways to self-manage symptoms and  
improve overall HRQL. iP2P mentoring combined with TTC also has the potential to reduce  
the burden on services.

Based on our qualitative need assessment, the Canadian TTC website's 3 basic components  
have been culturally adapted:

1. Disease specific content (what is JIA, how is it diagnosed, how is it treated using  
pharmacological, physical and psychological strategies);
2. Developing self-management skills to live well with JIA (managing emotions, managing  
physical symptoms, healthy life style, skills to move on to adult health care, education and  
vocational skills to manage JIA);
3. Social support (videos, and stories of hope).

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5 This study will examine if greater reach and adoption of self-management and peer support  
6 programmes are achievable using novel information and communication technologies (i.e., e-  
7 Health).  
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### 10 11 12 **Objective:**

13 To explore feasibility and preliminary effectiveness of iP2P mentoring programme along with  
14 an Irish version of “Teens Taking Charge: Managing Arthritis Online” to help adolescents with  
15 JIA improve their self-management skills, HRQL, disease knowledge, social support, self-  
16 efficacy, physical symptoms and emotional distress, compared to a treatment as usual control  
17 group.  
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### 23 24 **Hypotheses:**

- 25 1. A feasible Internet self-management programme alongside a peer support intervention  
26 will provide Irish adolescents with JIA evidenced-based arthritis self-management and  
27 transitional care knowledge and skills.  
28
- 29 2. The involvement of the Young People Advisory Panel as well as Arthritis Ireland (AI)  
30 and iCAN (collaborators on the Lending an Ear project) will support a successful,  
31 sustainable and adolescent-appropriate launch of the adjusted Irish TTC and peer  
32 support programme.  
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### 39 40 **Methods and Analysis**

#### 41 *Patient and Public Involvement*

42 Before designing the pilot RCT we worked with adolescents with JIA their parents and HCP  
43 to explore their experiences of living with JIA, levels of support and medications within the  
44 Irish system and to explore whether interventions such as TTC and iP2P would be welcomed  
45 and useful to them.<sup>13</sup>  
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50 Once we knew that the interventions would be positively received and of use to our target  
51 population we invited adolescents and their parents to be part of a Young Persons’ Advisory  
52 Panel (YPAP) from the start of the research process.  
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55 All stakeholders were involved in the adaption of the on-line programme, recruitment of the  
56 mentors and trialling of the adapted on-line programme, design of recruitment posters and the  
57 measures we will be using on-line pre and post the intervention.  
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3 The YPAP met initially – courtesy of their parents bringing them to a central location - for a  
4 day's training as a research support panel and now meet either via WhatsApp or schedules  
5 ZOOM meetings.  
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8 See our dissemination plans for how study participants will be kept informed of the progress  
9 of the study and our results.  
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12 Hence, from the start of this process, stakeholder have reviewed several times the on-line  
13 intervention, and given us feedback on how to ensure it is both acceptable and accessible to  
14 the Irish target population of teens with JIA and their parents.  
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### 18 ***Study design***

19 A single-blinded (outcome assessment), pilot RCT design with three arms (20 teens in each) to  
20 test the feasibility and effectiveness of the Irish adapted TTC with and without integrated iP2P  
21 intervention for a 12-week period.  
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### 25 ***Participant Eligibility***

#### 26 *Inclusion criteria:*

- 27 • Adolescents between 12-18 years of age
- 28 • Parental consent for teen to participate
- 29 • Adolescents diagnosed with and actively being treated for JIA
- 30 • Parent and adolescent are both able to speak and read English
- 31 • Access to a computer, smartphone or tablet capable of using free Skype software
- 32 • Be willing and able to complete online measures
- 33 • Adolescent will be eligible to participate without the participation of a parent

#### 34 *Exclusion criteria*

- 35 • Major cognitive impairments – based on medical assessments
- 36 • Co-morbid medical or psychiatric illnesses which may impact on ability to understand  
37 and use web-based programmes – based on medical assessments
- 38 • Parents/caregivers will not be eligible to participate in the study alone (without an  
39 adolescent)

### 40 ***Recruitment***

41 Three recruitment avenues to secure sufficient participants:

42 i) OLCH Crumlin: All registered and eligible patients of the Paediatric Rheumatology  
43 programme will be sent an invitation to participate. This method will be supplemented by  
44 purposive sampling of patients attending regularly scheduled clinic visits, to achieve desired  
45 number of participants.  
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3 ii) AI and iCAN: Both organisations will be asked to inform their members of the study.  
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5 iii) Social media: The study will be advertised through various social media channels  
6 (Facebook, Twitter etc.).  
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### 8 ***Randomisation***

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10 When a participant agrees to take part in the trial they will be randomly assigned to one of the  
11 three arms using random permuted blocks to ensure groups are balanced. Randomisation will  
12 be performed using a custom-written script, administered from a password-secured server. As  
13 such, researchers will not hold influence in the allocation process.  
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### 16 ***Description of study arms***

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18 (a) The control group will receive their usual healthcare appointments, medication and  
19 therapies.  
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21 (b) Experimental groups  
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  - 24 ● *For both intervention groups (TTC alone and iP2P-TTC)*

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26 In addition to standard medical care, adolescents with JIA in the two experimental groups will  
27 receive interactive multi-component self-guided online TTC intervention which consists of 12  
28 modules for teens. There are also two modules specifically for parents/care-givers to help  
29 encourage healthy behaviour.  
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32 The TTC programme will be delivered on restricted password-protected website that allows  
33 the team to track usage. The TTC programme is set up in a modular fashion; participants work  
34 through over a 15-week period at their own pace. Adolescents will be encouraged to log onto  
35 the website and complete one module per week. However, website activity will be flexible, and  
36 adolescents will be able to catch up missed modules (e.g. due to feeling unwell, exams, holidays  
37 etc.). A 91% (20/22) compliance was achieved in adolescents with JIA within the experimental  
38 group in the pilot RCT of the original TTC.<sup>6</sup> Consequently, for both TTC alone and integrated  
39 iP2P-TTC groups, data from participants completing at least 70% of the TTC programme will  
40 be considered valid for analyses.  
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  - 44 ● *iP2P -TTC*

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46 As well as access to TTC each participant will be matched with a peer mentor. Mentors  
47 identified by HCP or the support groups (AI and iCAN) will have undergone 2 days training  
48 and Gardaí vetting prior to the programme. They will have SKYPE calls with their mentees for  
49 up to an hour every week. There will be flexibility in number of sessions a dyad will have (in  
50 Canadian pilot RCT males preferred fewer sessions).<sup>11</sup> However, we will advise weekly  
51 contact. The aim will be for a maximum of 12 calls within a 15-week period.  
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### Sample Size and Power Estimations.

**Pilot RCT:** It is suggested that between 20 and 30 participants be recruited per group for pilot studies to examine overall feasibility and for development of estimates (e.g. variance) to compute power for a larger trial.<sup>14,15</sup> Therefore, we will recruit a total of 60 12-18-year-old participants (20 in each arm) and their primary caregivers.

**Mentors for iP2P:** At least 5 17-26-year-olds – will complete a previously validated 2-day training course (organised in collaboration between co-applicants, Drs. Stinson and Kohut and collaborators AI and iCAN), and supported throughout the duration of the study (e.g. consultations with research staff, additional training in mentorship skills if needed).

**Young Person Advisory Panel:** 5 12-20-year-olds will receive a day of training in research methods and exploration of their role as a team of experts in the study, and meet, both face-to-face and via Zoom, regularly over the course of the study. Our commitment to PPI, is based on ensuring our research results do enhance peoples' lives. So following the needs assessment with all the stakeholders, it was vital to ensure that teens with JIA and their families retained a voice in the development of all materials and rollout of the pilot RCT.

### Study Monitoring Procedures

In addition to the input from the YPAP, 'Lending an Ear' will have monthly meetings between all co-applicants and collaborators to ensure their expertise continues to inform challenge resolutions and progression.

### Measures

#### (A) *Feasibility Outcomes:*

1. *Participant accrual and dropout rates* will be centrally tracked by postdoctoral researcher and RA.
2. *Fidelity:* Any issues or difficulties encountered during implementation of interventions, control strategy, or outcome measures will be tracked throughout the study.
3. *Acceptability and Satisfaction* with interventions:
  - Post-treatment, adolescents with JIA and their parents in the TTC and iP2P-TTC intervention groups will rate acceptability of and satisfaction with the intervention.
  - Satisfaction with TTC and the integrated iP2P-TTC programme will also be captured using semi-structured interviews at study completion with 4-6 adolescent-parent dyads (chosen via random numbers list) who were randomised to the groups. Broader

assessment of engagement (e.g., most helpful aspects, enjoyment, how tailoring was done) will be part of the semi-structured interviews.

- All participants randomised to the integrated iP2P-TTC will also be given a measure of mentor quality (Mentor Behaviour Scale) immediately following completion, to rate the quality of their received mentorship.
- Mentors will complete measures to assess their views on the iP2P training and be invited to a group session post intervention to explore their ideas on the whole programme.

#### 4. *Engagement with interventions:*

- Google Analytics will be used to track patterns of website programme usage by adolescents with JIA and parents (e.g., which TTC modules have been accessed and in what order) in the TTC alone group.
- For participants in the integrated iP2P-TTC intervention the order and amount of used TTC modules, number of calls with mentor, length of calls and discussed topics will be tracked.
- In addition, Medical Issues, Exercise, Pain and Social Support Questionnaire (MEPS)<sup>16</sup> questionnaire (see effectiveness outcomes) will provide information on improved knowledge.

#### 5. *Tailoring:*

To evaluate whether the iP2P component facilitates tailoring of the intervention to the needs of each teen, we will track for both intervention groups which modules they have visited and in which order. In addition, during the semi-structured interviews with mentors and mentees we will ask more details on how exactly this tailoring took place.

#### **(B) Effectiveness Outcomes:**

*Adolescent will complete measures evaluating:*

- Self-management (TRANSITION-Q)<sup>17</sup> 3 point scale, 14 items.
- HRQL (PedsQL Arthritis Module)<sup>18</sup> 5 point scale, 5 areas: Problem with Pain & Hurt (4 items), Problems with Daily Activities (5 items).
- Pain (PROMIS Pediatric Profile Pain Intensity and Interference scales)<sup>19</sup> 5 point scale, (8 items).
- Revised Children's Anxiety and Depression Scale (RCADS)<sup>20, 21</sup> - 25 items, with subscale scores for depression and anxiety as well as an overall internalising score.

- Disease knowledge (MEPS)<sup>16</sup> 10 point scale, 4 areas: Medical Issues (9 items), Exercise (4 items), Pain (6 items) Social Support (4 items)
- Self-efficacy (Children's Arthritis Self-Efficacy; CASE)<sup>22</sup> 5 point scale, (11 items)
- Perceived social support (PROMIS Paediatric Profile Peer Relationship Scale).<sup>23</sup> Short form 5 point scale, (8 items)
- Health Services Use and Out-of-Pocket Expense Diary-Youth Version<sup>24</sup> 10 different areas: Extracurricular activities (2 items), Academic activities (6 items) Loss of time (5 items), Contact with medical doctor (5 items), Allied health professionals and social service providers (2 Items), Emergency room visits (7 items), Hospital admissions (3 items), Medication (2 items), Medical devices (2 items), Parent loss of time from work (pain or unpaid) (16 items). Measure was adapted from health economist's thesis project.

*Parents will complete measures assessing adolescents:*

- HRQL (PedsQL Arthritis Module).<sup>18</sup>
- Adherence (Adherence report questionnaire; PARQ)<sup>25</sup> 1-7 measures, scale of 10
- Medical issues (Medical Issues Questionnaire)<sup>16</sup> (9 items).
- Self-efficacy (Parent Arthritis Self-Efficacy; PASE)<sup>22</sup> 14 measures, 0-7 point scale from very uncertain to certain.

*Mentors will complete in relation to their own abilities:*

- Ability to Participate in Social Roles and Activities – PROMIS Short Form 8a - 10 point scale, (8 items); Exercise regularly Scale (3 items); Get information about disease (1 item); Obtain help from community, family, friends (4 items); Communicate with Physician (3 items); Manage disease in General (5 items); Do chores (3 items); Social/recreational Activities (2 items); manage symptoms (5 items); Manage shortness of breath (1 item); Control/manage depression (6 items).
- Chronic Disease Self-Efficacy Scale, 5 point scale, 10 areas.
- PROMIS–29 Profile v2.0.<sup>19</sup> 5 point scale 8 areas: Physical function (4 items), anxiety (4 items), Depression (4 items), fatigue (4 items), sleep disturbance (4 items), ability to participate in social roles and activities (4 items), Pain interference (4 items), Pain intensity on a scale of 1 – 10 (1 item).

- iPeer2Peer Mentor Training Evaluation 5 point scale, 10 items <sup>11</sup>
- Post-intervention Semi-structured Focus Group to explore their perspectives on how well the programme worked for the mentees and themselves.

*In addition to completing effectiveness outcome measures of TTC, mentees will also complete:*

- Mentor Behaviour Scale - 5 point scale of 4 areas: Structure (8 items), Engagement (2 items), Autonomy support (2 items), and Competency Support (3 items) <sup>26</sup>

All measures have evidence of reliability and validity in samples of adolescents with JIA.

### **Background measures**

For descriptive purposes and to obtain information on potential moderators of the strength of observed treatment effects, the following variables will be assessed at baseline:

- Adolescent and parent socio-demographic and JIA-related characteristics. Because this intervention is designed to be an adjunct to usual management approaches for JIA, participants will not be excluded if they are receiving common medical and physically based therapies. Information will be collected at each outcome measurement time point on whether participants in any group used or sought out any adjunct therapies (e.g. medications, physical, psychological and complementary/alternative therapies), social support (e.g. Facebook or Instant Messaging), disease specific information or attendance at a support group camp during the study period, to determine their extent of use.
- Access, use, and comfort level with computers and the Internet,
- Expectation about treatment effectiveness from adolescents and parents (using numerical rating scale - 0='don't think it will help at all' to 10='think it will help a lot').

### **Retention and Adherence**

Adolescents will be encouraged to log onto the website once per week for 12 weeks and complete one module per week.

If a mentor/mentee dyad has not had a call within 2 weeks but has not indicated to the RA that they have terminated the programme, the RA will contact the participant to determine interest in continuing versus terminating their involvement or if they prefer to continue with just TTC programme. If they have decided to end the programme they will be asked to fill out outcome measures. If scheduled calls are missed, participants will receive reminders by the mentor

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3 and/or the RA via email, text, or phone. We will control for the number of Skype calls made in  
4 the analyses.  
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6 Characteristics of adherent versus non-adherent participants will be examined for systematic  
7 differences; when found, analyses will be conducted to determine effect on outcomes.  
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### 10 ***Losses to Follow-up***

11 Every effort will be made to retain participants in the study groups and to obtain post-treatment  
12 measures on all who enrolled. We will ask for multiple phone numbers (home, mobile phone)  
13 and/or email addresses, which will aid follow-up. To minimize losses to follow-up, the RA may  
14 make calls, texts and emails to remind participants of timing of various online assessments.  
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### 20 **Data Analysis**

21 All semi-structured interviews will be audio-taped and transcribed verbatim to determine  
22 satisfaction with the Irish TTC or TTC + iP2P programme.<sup>6</sup> The transcribed data will be  
23 managed using NVivo 11 computer software programme, which allows for online coding and  
24 annotation of text. We will use content analyses as outlined by Elo and Kygnäs, (2008).<sup>27</sup>  
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29 Quantitative data will be analysed using SPSS version 21. Descriptive statistics will be used to  
30 describe sample characteristics at baseline. Rates of accrual drop out, compliance, and missing  
31 data with 95% confidence intervals will be calculated. The normality of the data will be  
32 assessed using histograms and normal probability plots and if assumptions are met, then a  
33 parametric statistics approach will be taken to analysis.  
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38 To inform sample size calculations and data analysis for a larger trial, data will be analysed as  
39 in a larger study, and estimates of variance and correlation (i.e., intra-cluster correlation within  
40 site) on physical (pain, fatigue) and emotional (anxiety, depression) symptoms, perceived  
41 social support, self- efficacy, adherence, knowledge, and HRQL will all be estimated. Analysis  
42 will be conducted using an intent-to-treat approach. If assumptions for parametric statistics are  
43 met, linear mixed models will be used to test intervention effects on outcomes using an analysis  
44 of covariance approach with post-treatment measures compared between groups using baseline  
45 scores as covariates. To control for type 1 error rate, Holm's Sequential correction will be  
46 applied. We will use the SPIRIT <sup>28</sup> reporting guidelines to report this trial.  
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53 Cost effectiveness and cost utility analyses will be conducted using both a healthcare system  
54 and societal perspective. Cost effectiveness and cost utility will be expressed as incremental  
55 cost effectiveness ratios (ICERs),<sup>29</sup> calculated by dividing the incremental costs between  
56 treatment arms by the incremental change in utility scores, measured as HRQL using the  
57 PedsQL. Multiple ICERS will be calculated comparing each of the three study groups in a  
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3 pairwise fashion for both the cost effectiveness and cost utility analyses. Extensive  
4 deterministic and probabilistic sensitivity analysis will be performed to evaluate the robustness  
5 of the results. A 95% confidence interval for incremental costs, incremental effects, and the  
6 ICER will be calculated from study data using bootstrapping.  
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### 10 11 **Data monitoring and management**

12 This study will collect non-identifying, minimally invasive information, which is not expected  
13 to cause any level of distress to participants. All data will be collected electronically and stored  
14 securely at the Centre for Pain Research on password-protected databases that can only be  
15 accessed by the research team.  
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18 Should any participant - parent, adolescent or young adult - indicate at any point during the  
19 study that they no longer wish to participate, that decision will be respected. If they would like  
20 to have their data up to that point destroyed or not used in the final analyses, they can inform  
21 the researcher of their wishes and their data will be confidentially shredded.  
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24 If an adolescent is found to be at risk, appropriate methods will be taken to inform those in  
25 positions of authority. The guidelines of the Child Protection Policy outlined by the respective  
26 hospital where the adolescent is being treated will be followed to ensure that they are fully  
27 supported throughout the project in relation to any issues that may arise. If an adolescent is  
28 considered to be at risk during the course of the project, a Senior Clinical Psychologist will be  
29 contacted by the researchers to provide appropriate guidance and consultation if necessary.  
30  
31

32 In accordance with the Ethical Guidance for research with children, all members of the research  
33 team will be Garda vetted and employment checks will be carried out.  
34  
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36 All members of the research team will be trained and have access to relevant expertise in  
37 relation to child protection issues. All those researchers having face-to-face contact with the  
38 adolescents will have taken part in HSE Child First training.  
39  
40

41 Additionally, written consent and assent will be obtained from all participating adolescents,  
42 their parents and the young adult mentors. During the consent process, the study procedures  
43 will be described in detail to both parents and adolescents, giving each individual time to read  
44 the information and the opportunity to ask questions. Adolescents and parents will also be  
45 advised that they are able to stop their participation at any time.  
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### 56 **Dissemination**

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We will use both integrative and end-of-project knowledge exchange approaches to disseminate the findings to the public, patients with JIA and their families, support organisations, researchers and clinicians.

*Approach 1 will include:*

(a) Involving key stakeholders in all stages of the research process from the outset. Key stakeholders include adolescents with JIA (represented by the YPAP, patient organisations (e.g., AI, and iCAN), and clinicians).

(b) Presentation of research findings by the PI and co-applicants at National, European and International conferences, plus published in leading paediatric or rheumatology journals to target all practicing health care professionals.

(c) Other strategies will include a 1-page report and YouTube video that will be:

1. Distributed to rheumatology health care professionals and patient groups across Ireland,
2. Included in media releases and posting/links on key websites (e.g., <http://www.juvenilearthritis.ie>) and social media,
3. Sent to all participants at the end of the project to inform them of the findings,
4. Included in conference presentations, which will be co-presented by researchers and stakeholders (e.g., adolescents with JIA, Arthritis Ireland or iCAN representative) where possible.

*Approach 2 will involve:* launching an interactive Internet conduit (“Irish Teens Taking Charge: Managing Arthritis Online” and peer mentoring) at the end of the project, if found to be effective, to share knowledge with users, predominately adolescents with JIA and their families, as well as other web audiences (e.g., peers, teachers, and health professionals).

This mode of communication can provide an effective tool to help in the collection, processing and targeted distribution of information about JIA research to benefit patients and their families, clinicians, researchers, administrators, health care policy makers, school administrations and the public.

**We used the SPIRIT reporting guidelines where applicable for a pilot RCT.** <sup>30</sup>

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All our collaborators and funders.

iCAN, Arthritis Ireland, all the families and HCP who are working with us on this project



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**Conflict of interest:**

There are no conflicts of interest

**Authors Statement:**

All the authors work on this study. Each author reviewed the initial text and made substantial contributions and changes to create this final draft.

**Trial Registration**

The pilot RCT is being registered with ISRCTN.

## References

1. Arthritis Ireland (2017). Retrieved from: <http://www.juvenilearthritis.ie>
2. Sawyer, M. G., Whitham, J. N., Robertson, D. M., Taplin, J. E., Varni, J. W., & Baghurst, P. A. (2004). The relationship between health-related quality of life, pain and coping strategies in juvenile idiopathic arthritis. *Rheumatology*, *43*(3), 325-330.
3. Stinson, J., Kohut, S. A., Forgeron, P., Amaria, K., Bell, M., Kaufman, M. & Spiegel, L. (2016). The iPeer2Peer program: a pilot randomized controlled trial in adolescents with juvenile idiopathic arthritis. *Pediatric Rheumatology*, *14*(1), 48.
4. Simons, L.E., Logan, D.E., Chastain, L. & Cerullo, M. (2010). Engagement in Multidisciplinary interventions for pediatric chronic pain: parental expectations, barriers, and child outcomes. *Clinical Journal of Pain*, *26*, 291–299.
5. Stinson, J., McGrath, P., Hodnett, E., Feldman, B., Duffy, C., Huber, A. & Campillo, S. (2010). Usability testing of an online self-management program for adolescents with juvenile idiopathic arthritis. *Journal of Medical Internet Research*, *12*(3), e30.
6. Stinson, J. N., McGrath, P. J., Hodnett, E. D., Feldman, B. M., Duffy, C. M., Huber, A. M. & Campillo, S. (2010). An internet-based self-management program with telephone support for adolescents with arthritis: a pilot randomized controlled trial. *The Journal of Rheumatology*, *37*(9), 1944-1952.
7. Dennis, C.L. (2003). Peer support within a health care context: A concept analysis. *International Journal of Nursing Studies*, *40*(3), 321–332.
8. Kohut, S. & Stinson, J. (2014). Systematic review of peer support interventions for adolescents with chronic illness: A narrative analysis. *International Journal of Child and Adolescent Health*, *7*, 183-197.
9. Sandhu, S., Veinot, P., Embuldeniya, G., Brooks, S., Sale, J., Huang, S. & Bell, M. J. (2013). Peer-to-peer mentoring for individuals with early inflammatory arthritis: feasibility pilot. *BMJ open*, *3*(3), e002267.
10. Zelikovsky, N. & Petrongolo, J. (2013). Utilizing peer mentors for adolescents with chronic health conditions: Potential benefits and complications. *Pediatric transplantation*, *17*(7), 589-591.
11. Kohut, S. A., Stinson, J. N., Ruskin, D., Forgeron, P., Harris, L., van Wyk, M. & Campbell, F. (2016). iPeer2Peer program: a pilot feasibility study in adolescents with chronic pain. *Pain*, *157*(5), 1146-1155.
12. Ford P. (2017). The app route to patient engagement. *HIMSS Europe*, *5*(3),

- 1  
2  
3 16-17  
4  
5 13. O'Sullivan, G., O'Higgins, S., Caes L., Saetes, S., McGuire, B.E., & Stinson, J., (accepted  
6 October 2018). Self-management needs of Irish adolescents with Juvenile Idiopathic Arthritis  
7 (JIA): how can a Canadian web-based programme meet these needs? *Journal of Pediatric*  
8 *Rheumatology*.  
9  
10  
11  
12 14. Hertzog, M.A. (2008). Considerations in determining sample size for pilot  
13 studies. *Research in Nursing & Health*, 31, 180–191.  
14  
15 15. Arain, M., Campbell, M. J., Cooper, C. L. & Lancaster, G. A. (2010). What is a pilot  
16 or feasibility study? A review of current practice and editorial policy. *BMC medical*  
17 *research methodology*, 10(1), 67.  
18  
19 16. André M, Hedengren E, Hagelberg S, Stenström CH. Perceived ability to manage  
20 juvenile chronic arthritis among adolescents and parents: development of a  
21 questionnaire to assess medical issues, exercise, pain, and social support. *Arthritis Care*  
22 *Res.* 1999;12(4):229-237.  
23  
24 17. Klassen AF, Grant C, Barr R, et al. Development and validation of a generic scale for  
25 use in transition programmes to measure self-management skills in adolescents with  
26 chronic health conditions: the TRANSITION-Q. *Child Care Health Dev.*  
27 2014;41(4):547-558.  
28  
29 18. Varni, W. J., Seid, M., Smith Knight, T., Burwinkle, T., Brown, J., Szer, I., The  
30 PedsQL™ in pediatric rheumatology: Reliability, validity, and responsiveness of the  
31 Pediatric Quality of Life Inventory™ Generic Core Scales and Rheumatology Module.  
32 *Arthritis & Rheumatology* 2002; 46(3):714-25.  
33  
34 19. Jacobson, C.J., Kashikar-Zuck, S., Farrell, J., Barnett, K., Goldschneider, K., Dampier,  
35 C., Cunningham, N., Crosby, L. & DeWitt, E.M. (2015). Qualitative evaluation of  
36 pediatric pain, behavior, quality and intensity item candidates and the PROMIS pain  
37 domain framework in children with chronic pain. *J Pain.* 16(12), 1243-55.  
38  
39 20. Chorpita, B. F., Yim, L., Moffitt, C., Umemoto, L. A., Francis, S. E., Assessment of  
40 symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and  
41 depression scale. *Behaviour Research and Therapy.* 2000; 38(8), 835-855.  
42  
43 21. Chorpita, B. F., Ebesutani, C., Spence, S., Revised Children's Anxiety and  
44 Depression Scale, User Guide. 2015 downloaded from [www.childfirst.ucla.edu](http://www.childfirst.ucla.edu)  
45 22.04.2018.  
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22. Brady Teresa J. (2011) Measures of self-efficacy: Arthritis Self-Efficacy Scale (ASES), Arthritis Self-Efficacy Scale-8 Item (ASES-8), Children's Arthritis Self-Efficacy Scale (CASE), Chronic Disease Self-Efficacy Scale (CDSSES), Parent's Arthritis Self-Efficacy Scale (PASE), and Rheumatoid Arthritis Self-Efficacy Scale (RASE). *Arthritis Care & Research*. 2011; 63 (S11): S473-
  23. DeWalt DA, Thissen D, Stucky BD, Langer MM. PROMIS pediatric peer relationships scale: Development of a peer relationships item bank as part of social health measurement. *Health Psychology*. 2013; 32(10):1093-1103.
  24. Moretti ME A cost-effectiveness analysis of maternal genotyping to guide treatment for postpartum pain and avert infant adverse events. [PhD Dissertation] Toronto, Canada: Institute of Health Policy Management and Evaluation, University of Toronto; 2014.
  25. De Civita, M., Dobkin, P., Ehrmann-Feldman, D., Karp, I., Duffy, C. Development and Preliminary Reproducibility and Validity of the Parent Adherence Report Questionnaire: A Measure of Adherence in Juvenile Idiopathic Arthritis. *Journal of Clinical Psychology in Medical Settings*. 2005; 12(1): 1-12.
  26. Brodeur P, Larose S, Tarabulsy G, Feng B, Forget-Dubois N. Development and Construct Validation of the Mentor Behavior Scale. *Mentoring & Tutoring: Partnership in Learning*. 2015;23(1):54-75.
  27. Elo, S. & Kyngäs, H. (2008). The qualitative content analysis process. *Journal of Advanced Nursing*, 62(1), 107-115.
  28. <http://www.spirit-statement.org>
  29. Bensink, M., Wootton, R., Irving, H., Hallahan, A., Theodoros, D., Russell, T. & Barnett, A. G. (2007). Investigating the cost-effectiveness of video telephone based support for newly diagnosed paediatric oncology patients and their families: design of a randomised controlled trial. *BMC health services research*, 7(1), 38.
  30. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158(3):200-207.

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		Reporting Item	Page Number
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	14
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	<a href="#">#3</a>	Date and version identifier	
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	14
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	1,14

1	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	14
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7				
8	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	n/a
9	responsibilities:		design; collection, management, analysis, and	
10	sponsor and funder		interpretation of data; writing of the report; and the	
11			decision to submit the report for publication, including	
12			whether they will have ultimate authority over any of	
13			these activities	
14				
15				
16				
17	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the	n/a
18	responsibilities:		coordinating centre, steering committee, endpoint	
19	committees		adjudication committee, data management team, and	
20			other individuals or groups overseeing the trial, if	
21			applicable (see Item 21a for data monitoring committee)	
22				
23				
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25				
26	Background and	<a href="#">#6a</a>	Description of research question and justification for	3-5
27	rationale		undertaking the trial, including summary of relevant	
28			studies (published and unpublished) examining benefits	
29			and harms for each intervention	
30				
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32				
33	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	6-10
34	rationale: choice of			
35	comparators			
36				
37				
38	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	5
39				
40	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg,	5
41			parallel group, crossover, factorial, single group),	
42			allocation ratio, and framework (eg, superiority,	
43			equivalence, non-inferiority, exploratory)	
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47	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	7
48			academic hospital) and list of countries where data will	
49			be collected. Reference to where list of study sites can	
50			be obtained	
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54	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If	5-6
55			applicable, eligibility criteria for study centres and	
56			individuals who will perform the interventions (eg,	
57			surgeons, psychotherapists)	
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1	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow	6-7
2	description		replication, including how and when they will be	
3			administered	
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5				
6	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated	n/a
7	modifications		interventions for a given trial participant (eg, drug dose	
8			change in response to harms, participant request, or	
9			improving / worsening disease)	
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12				
13	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention	7,11
14	adherence		protocols, and any procedures for monitoring adherence	
15			(eg, drug tablet return; laboratory tests)	
16				
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18	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are	n/a
19	concomitant care		permitted or prohibited during the trial	
20				
21				
22	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the	8-11
23			specific measurement variable (eg, systolic blood	
24			pressure), analysis metric (eg, change from baseline,	
25			final value, time to event), method of aggregation (eg,	
26			median, proportion), and time point for each outcome.	
27			Explanation of the clinical relevance of chosen efficacy	
28			and harm outcomes is strongly recommended	
29				
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33	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any	5
34			run-ins and washouts), assessments, and visits for	
35			participants. A schematic diagram is highly	
36			recommended (see Figure)	
37				
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40	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve	7
41			study objectives and how it was determined, including	
42			clinical and statistical assumptions supporting any	
43			sample size calculations	
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47	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment	11
48			to reach target sample size	
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51	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence (eg,	6
52	generation		computer-generated random numbers), and list of any	
53			factors for stratification. To reduce predictability of a	
54			random sequence, details of any planned restriction (eg,	
55			blocking) should be provided in a separate document that	
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is unavailable to those who enrol participants or assign interventions

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4	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg, 6
5	concealment		central telephone; sequentially numbered, opaque,
6	mechanism		sealed envelopes), describing any steps to conceal the
7			sequence until interventions are assigned
8			
9			
10	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol 6
11	implementation		participants, and who will assign participants to
12			interventions
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16	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg, 6
17			trial participants, care providers, outcome assessors,
18			data analysts), and how
19			
20			
21	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is 6
22	emergency		permissible, and procedure for revealing a participant's
23	unblinding		allocated intervention during the trial
24			
25			
26	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, 8-11
27			baseline, and other trial data, including any related
28			processes to promote data quality (eg, duplicate
29			measurements, training of assessors) and a description
30			of study instruments (eg, questionnaires, laboratory
31			tests) along with their reliability and validity, if known.
32			Reference to where data collection forms can be found, if
33			not in the protocol
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39	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and complete 11
40	retention		follow-up, including list of any outcome data to be
41			collected for participants who discontinue or deviate from
42			intervention protocols
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46	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, 11-13
47			including any related processes to promote data quality
48			(eg, double data entry; range checks for data values).
49			Reference to where details of data management
50			procedures can be found, if not in the protocol
51			
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54	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary 11-12
55			outcomes. Reference to where other details of the
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1			statistical analysis plan can be found, if not in the	
2			protocol	
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4	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and	n/a
5	analyses		adjusted analyses)	
6				
7				
8	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-	11
9	population and		adherence (eg, as randomised analysis), and any	
10	missing data		statistical methods to handle missing data (eg, multiple	
11			imputation)	
12				
13				
14	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC);	n/a
15	formal committee		summary of its role and reporting structure; statement of	
16			whether it is independent from the sponsor and	
17			competing interests; and reference to where further	
18			details about its charter can be found, if not in the	
19			protocol. Alternatively, an explanation of why a DMC is	
20			not needed	
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26	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping	n/a
27	interim analysis		guidelines, including who will have access to these	
28			interim results and make the final decision to terminate	
29			the trial	
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33	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing	n/a
34			solicited and spontaneously reported adverse events and	
35			other unintended effects of trial interventions or trial	
36			conduct	
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40	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if	n/a
41			any, and whether the process will be independent from	
42			investigators and the sponsor	
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45	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee /	2
46	approval		institutional review board (REC / IRB) approval	
47				
48				
49	Protocol	<a href="#">#25</a>	Plans for communicating important protocol modifications	n/a
50	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
51			relevant parties (eg, investigators, REC / IRBs, trial	
52			participants, trial registries, journals, regulators)	
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55	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential	13
56			trial participants or authorised surrogates, and how (see	
57			Item 32)	
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1	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of	n/a
2	ancillary studies		participant data and biological specimens in ancillary	
3			studies, if applicable	
4				
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6	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled	12
7			participants will be collected, shared, and maintained in	
8			order to protect confidentiality before, during, and after	
9			the trial	
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13	Declaration of	<a href="#">#28</a>	Financial and other competing interests for principal	14
14	interests		investigators for the overall trial and each study site	
15				
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17	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial	14
18			dataset, and disclosure of contractual agreements that	
19			limit such access for investigators	
20				
21				
22	Ancillary and post	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for	n/a
23	trial care		compensation to those who suffer harm from trial	
24			participation	
25				
26				
27	Dissemination	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial	13-14
28	policy: trial results		results to participants, healthcare professionals, the	
29			public, and other relevant groups (eg, via publication,	
30			reporting in results databases, or other data sharing	
31			arrangements), including any publication restrictions	
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36	Dissemination	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of	n/a
37	policy: authorship		professional writers	
38				
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40	Dissemination	<a href="#">#31c</a>	Plans, if any, for granting public access to the full	n/a
41	policy: reproducible		protocol, participant-level dataset, and statistical code	
42	research			
43				
44				
45	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation	Appendix
46	materials		given to participants and authorised surrogates	
47				
48				
49	Biological	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of	n/a
50	specimens		biological specimens for genetic or molecular analysis in	
51			the current trial and for future use in ancillary studies, if	
52			applicable	
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# BMJ Open

## LENDING AN EAR: IPEER2PEER PLUS TEENS TAKING CHARGE ONLINE SELF-MANAGEMENT TO EMPOWER ADOLESCENTS WITH ARTHRITIS. PROTOCOL FOR A PILOT RCT.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-027952.R1
Article Type:	Protocol
Date Submitted by the Author:	08-May-2019
Complete List of Authors:	O'Higgins, Siobhan; National University of Ireland, Galway, Centre for Pain Research, School of Psychology Stinson, Jennifer; University of Toronto, Faculty of Nursing ; Hospital for Sick Children Ahola Kohut, Sara; University of Toronto, Faculty of Nursing ; Hospital for Sick Children, Medical Psychiatry Alliance Caes, Line; University of Stirling , Division of Psychology, Faculty of Natural Sciences Heary, Caroline; National University of Ireland, School of Psychology McGuire, Brian; National University of Ireland, Galway, Ireland, School of Psychology & Centre for Pain Research
<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Paediatrics
Keywords:	Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, Information technology < BIOTECHNOLOGY & BIOINFORMATICS, Paediatric rheumatology < PAEDIATRICS, Juvenile Rheumatoid Arthritis, Adolescent Stakeholder involvement, Quality of life, Self-care, Online interventions

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Manuscripts

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2  
3 **LENDING AN EAR: IPEER2PEER PLUS TEENS TAKING CHARGE ONLINE**  
4 **SELF-MANAGEMENT TO EMPOWER ADOLESCENTS WITH ARTHRITIS.**  
5 **PROTOCOL FOR A PILOT RCT.**  
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## Abstract

### Introduction:

Juvenile Idiopathic Arthritis (JIA) negatively affects adolescents' everyday activities. To address the need for innovative, effective, convenient, low-cost psychosocial self-management programmes, we developed an Irish version of Canadian Teens Taking Charge (TTC) and integrated it with skype-based peer support iPeer2Peer (iP2P).

### Objectives:

- Explore feasibility and preliminary outcome impact (effectiveness) of an integrated iP2P and Irish TTC, via 3- arm (treatment as usual, TTC and iP2P-TTC) pilot RCT;
- Determine feasibility and sample size for a full RCT;
- Ensure active involvement of adolescents with JIA via a Young Person Advisory Panel (YPAP).
- To examine how participants experienced the study
- To see if TTC and iP2P with TTC reduce costs for families.

### Methods and analysis:

On-going recruited throughout 2019 until July, via HCP ad support groups until sample of 60 families engaged with the study.

Single-blinded (outcome assessment), 3-arm pilot RCT, using on-line questionnaires. Assessments at baseline (T1), after intervention (T2), and 3 months post-intervention (T3). Primary outcomes on feasibility: comparisons of TTC and iP2P-TTC on fidelity, acceptability and satisfaction, engagement, and degrees of tailoring.

Secondary outcomes: self-management and self-efficacy and a range of health-related quality of life factors, pain indicators, and costs.

Participants from intervention groups will be invited to share their perspectives on the process in semi-structured interviews.

Quantitative data analysed using SPSS version 21.

Qualitative data audio-taped, transcribed and analysed using qualitative content analysis.

Ethical approval: Research Ethics Committees - National University of Ireland, Galway and Our Lady's Children's Hospital (OLCH), Crumlin, and Temple Street Children's Hospital, Dublin.

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3 Dissemination: via journal articles, conference presentations, co-delivered by key stakeholders  
4 when possible, launch of accessible, effective and sustainable Internet self-management and  
5 peer support for Irish adolescents with JIA.  
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10 RCT Registration number: ISRCTN13535901  
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### 13 **Article Summary - Strengths and limitations** 14

- 15 • This study follows from an in-depth qualitative exploration of the need and desire  
16 among stakeholders for an on-line support programme.  
17
- 18 • The needs analysis offered suggestions on how to adapt the Canadian programme to  
19 ensure that the programme offered relevant information to the Irish context; these  
20 changes have been achieved.  
21
- 22 • Canadian TTC is known to improve the lives of teens with JIA and their families, this  
23 study builds on that success by adding extra elements of tailoring and sustainability  
24 with the iP2P peer mentoring.  
25
- 26 • Sustainability of the integrated programme, if found to be effective, is ensured due to:  
27 on-going collaboration with all stakeholders; Arthritis Ireland (a non-profit support  
28 service for people with Arthritis) taking over the peer mentoring element of the  
29 intervention, with on-going training and support for mentors, and; TTC will be up-dated  
30 biannually by About Kids Health in Toronto and Health Care Professionals in Ireland.  
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- 32 • Recruitment of sufficient teens and their families for the RCT may be difficult, hence  
33 active involvement of all stakeholders and the YPAP will be crucial to reach our target  
34 sample size.  
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### 45 **Introduction** 46

47 JIA is the most common childhood rheumatic disease. In Ireland 1,200 children live with JIA,  
48 with over 100 children newly diagnosed annually,<sup>1</sup> according to Arthritis Ireland (AI). Children  
49 and adolescents commonly experience a myriad of physical and emotional symptoms that  
50 restrict physical and social interactions and negatively impact their health-related quality of life  
51 (HRQL).<sup>2,3</sup> There is no cure, the disease course can be unpredictable, and HRQL deteriorates  
52 with increased disease severity, active joint counts, pain, and degree of disability.<sup>2,3</sup> The Irish  
53 rheumatologist to patient ratio for children with arthritis is second lowest in Europe, with  
54 waiting lists of up to 2 years; access to psychological support is equally limited. In addition,  
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3 transition to adult services is scheduled by age 16 years, rather than 18 in Canada. So, although  
4 cognitive-behavioural therapy (CBT) interventions can lead to improvement in pain and  
5 HRQL,<sup>4</sup> most young people with JIA in Ireland will not receive these interventions as teens  
6 although eventually they may avail of them through the adult rheumatology services. Hence,  
7 the need for supports to develop self-management skills for adolescents with JIA. Using the  
8 internet is a possible solution to address the gap between need, availability and access to  
9 effective treatments. Online interventions are scalable and accessible in the moment, 24 hours  
10 a day, and do not need therapist involvement.

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17 Prior to this study, our Canadian colleagues had evaluated the two programmes in the present  
18 study separately. Stinson and colleagues developed and tested the usability, feasibility and  
19 effectiveness of Teens Taking Charge (TTC), an online self-management programme  
20 consisting of 12 modules for teens and 2 for parents, with telephone support from a health  
21 coach (trained, adult non-Health Care Professionals (HCP) without arthritis) for Canadian  
22 adolescents with JIA.<sup>3,5,6</sup> Significant improvements were found in disease-related knowledge,  
23 decreased pain and increased exercise adherence.<sup>6</sup> Peer support by another person with similar  
24 chronic illness is associated with improved health outcomes.<sup>7-10</sup> iPeer2Peer (iP2P), an online  
25 peer mentoring programme, was evaluated with adolescents with chronic pain, and found to  
26 improve acceptability of self-management and peer support treatments.<sup>11</sup> Although positively  
27 evaluated separately working with teens with JIA the two programmes have not be combined  
28 before.

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Localising available and effective programmes which meet the specific needs of patients is an  
important development strategy for facilitating timely availability of evidence-based  
programmes.<sup>12</sup> Hence we conducted an Irish qualitative needs assessment working with  
members (teens and parents) of two patient organisations: Arthritis Ireland (AI), and Irish  
Children's Arthritis Network (iCAN, a support group set up by a parent as a support for other  
parents and teens with JIA); health care professionals from Our Lady's Children's Hospital  
(OLCH) Crumlin and other paediatric units. The interviews explored stakeholder perspectives  
on:

- Impact of JIA on adolescents and families
- Current Irish service provision
- The value and usability of Canadian "TTC: Managing Arthritis Online" and iP2P programmes

Lack of access to health services was the main concern of all stakeholders, especially non-availability of local multidisciplinary rheumatology teams. There was consensus that TTC



would be a useful resource for families and HCP once TTC information was tailored to the Irish context and specific needs of each patient, and facilitated through peer mentoring.<sup>13</sup>

These views taken together, underpin the critical need for accessible and effective interventions to assist Irish adolescents with JIA to find effective ways to self-manage symptoms and improve overall HRQL. iP2P mentoring combined with TTC also has the potential to reduce the burden on services, by providing information, support and empowerment tailored to the teens in- the- moment needs, reducing the need to contact HCP.

Based on our qualitative need assessment, and through further consultations with HCP, support services A.I and iCAN, the 5 teens with JIA who make up our Young Person Advisory Panel (YPAP), and their parents, the Canadian TTC website's 3 components which are encapsulated within the 12 modules, have been culturally adapted:

1. Disease specific content (what is JIA, how is it diagnosed, how is it treated using pharmacological, physical and psychological strategies);
2. Developing self-management skills to live well with JIA (managing emotions, managing physical symptoms, healthy life style, skills to move on to adult health care, education and vocational skills to manage JIA);
3. Social support (videos, and stories of hope).

Hence, the Irish TTC has videos of Irish teens with JIA and their parents and Irish Health Care Professionals talking about the different topics, integrated with videos of Canadians, spread throughout the 12 modules. The text has also been adapted with relevant to the drugs, service and financial support offered in Ireland rather than those in Canada. This process has taken us a year to achieve and Sick Kids Hospital has adapted the on-line TTC to incorporate all the changes that ensure the Irish TTC is acceptable and relevant to Irish families. The development of the pilot RCT can be seen in Figure 1.

This study will examine if greater reach and adoption of self-management and peer support programmes are achievable using novel information and communication technologies (i.e., e-Health), shown in Figure 2, as a schema of the pilot RCT<sup>14</sup>.

### **Objectives:**

- Explore feasibility and preliminary outcome impact (effectiveness) of an integrated iP2P and Irish TTC, via 3- arm (treatment as usual, TTC and iP2P-TTC) pilot RCT of “Teens Taking Charge: Managing Arthritis Online” to help adolescents with JIA improve their self-management skills, HRQL, disease knowledge, social support, self-



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3 efficacy, physical symptoms and emotional distress, compared to a treatment as usual  
4 control group.

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- 7 ● Determine feasibility and sample size for a full RCT;
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- 9 ● Ensure active involvement of adolescents with JIA throughout the study with creation  
10 and support of a Young Person Advisory Panel (YPAP), who communicate monthly  
11 with the research team via ZOOM calls and WhatsApp group messaging. They and  
12 their parents reviewed the videos and text of the Irish TTC, posters and all recruitment  
13 information sent out to parents and teens.
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- 15 ● To examine how participants experienced the study
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- 17 ● To see if TTC and iP2P and TTC reduce costs for families of teens with JIA.
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## 22 **Hypotheses:**

- 23
- 24 1. A feasible Internet self-management programme alongside a peer support intervention  
25 will provide Irish adolescents with JIA evidenced-based arthritis self-management and  
26 transitional care knowledge and skills; as well as the possibly of reducing HC costs for  
27 families.
- 28
- 29 2. The involvement of the YPAP, AI and iCAN (collaborators on the Lending an Ear  
30 project) will support a successful, sustainable and adolescent-appropriate launch of the  
31 adjusted Irish TTC and peer support programme.
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## 38 **Methods and Analysis**

### 39 *Patient and Public Involvement*

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41 Before designing the pilot RCT we worked with adolescents with JIA their parents and HCP  
42 to explore their experiences of living with JIA, levels of support and medications within the  
43 Irish system and to explore whether interventions such as TTC and iP2P would be welcomed  
44 and useful to them.<sup>13</sup>

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49 Once we knew that the interventions would be positively received and of use to our target  
50 population we invited adolescents and their parents to be part of a Young Persons' Advisory  
51 Panel (YPAP) from the start of the research process.

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55 All stakeholders were involved in the adaption of the on-line programme, recruitment of the  
56 mentors and trialling of the adapted on-line programme, design of recruitment posters and the  
57 measures we will be using on-line pre and post the intervention. Hosted by Limesurvey.

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3 The YPAP met initially – courtesy of their parents bringing them to a central location - for a  
4 day's training as a young research support panel. The group meet every month either via  
5 WhatsApp or scheduled ZOOM meetings, another face to face day is planned during school  
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7 holidays.  
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10 See our dissemination plans for how study participants will be kept informed of the progress  
11 of the study and our results.  
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14 Hence, from the start of this process, stakeholders have reviewed several times the on-line  
15 intervention, and given us feedback on how to ensure it is both acceptable and accessible to  
16 the Irish target population of teens with JIA and their parents.  
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### 20 ***Study design***

21 A single-blinded (outcome assessment), pilot RCT design with three arms (20 teens in each) to  
22 test the feasibility and effectiveness of the Irish adapted TTC with and without integrated iP2P  
23 intervention for a 12-week period.  
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### 27 ***Participant Eligibility***

#### 28 *Inclusion criteria:*

- 29 • Adolescents between 12-18 years of age
- 30 • Parental consent for teen to participate
- 31 • Adolescents diagnosed with and actively being treated for JIA
- 32 • Parent and adolescent are both able to speak and read English
- 33 • Access to a computer, smartphone or tablet capable of using free Skype software
- 34 • Be willing and able to complete online measures
- 35 • Adolescent will be eligible to participate without the participation of a parent

#### 36 *Exclusion criteria*

- 37 • Major cognitive impairments – based on medical assessments
- 38 • Co-morbid medical or psychiatric illnesses which may impact on ability to understand  
39 and use web-based programmes – based on medical assessments
- 40 • Parents/caregivers will not be eligible to participate in the study alone (without an  
41 adolescent)

### 42 ***Recruitment***

43 Three recruitment avenues to secure sufficient participants:

44 i) OLCH Crumlin: All registered and eligible patients of the Paediatric Rheumatology  
45 programme will be sent an invitation to participate, by the HCP. This method will be  
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3 supplemented by inviting patients attending regularly scheduled clinic visits, to achieve desired  
4 number of participants, by the research team.

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6 ii) AI and iCAN: Both organisations will be asked to inform their members of the study.

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8 iii) Social media: The study will be advertised through various social media channels  
9 (Facebook, Twitter etc.).

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11 For all routes of recruitment: once a parent emails or calls the Centre for Pain Research (CPR)  
12 for more information this will be sent out by the RA, with consent and assent forms for both  
13 parents and adolescent.

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15 It is not anticipated that the 3 processes will recruit sufficiently different types of teens –  
16 although those recruited by HCP may well be those with a more recent diagnosis. Date of  
17 diagnosis will be noted in their demographic survey and on consent and assent forms for future  
18 reference.

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20 All potential participants will be contacted, consent and assent forms as well as detailed  
21 information will be emailed or sent to each family, to be returned signed prior to randomisation.  
22 Recruitment in 2019 will continue until end of July 2019.

### 23 24 **Randomisation**

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26 When a participant agrees to take part in the trial they will be randomly assigned to one of the  
27 three arms using random permuted blocks to ensure groups are balanced. Randomisation will  
28 be performed using a custom-written script, administered from a password-secured server, by  
29 the CPR's medical statistician. As such, researchers will not hold influence in the allocation  
30 process. Participants will complete the initial on-line T1 measures and then once assigned to a  
31 group emailed with their specific details for involvement over the next 12 weeks.

### 32 33 **Description of study arms**

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35 (a) The control group will receive their usual healthcare appointments, medication and  
36 therapies, which may include physiotherapy, occupational therapy and talking with a  
37 psychologist (these may be organised by families rather than through the hospital).

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39 (b) Experimental groups

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41 • *For both intervention groups (TTC alone and iP2P-TTC)*

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43 In addition to standard medical care, adolescents with JIA in the two experimental groups will  
44 receive interactive multi-component self-guided online TTC intervention which consists of 12  
45 modules for teens. There are also two modules specifically for parents/care-givers to help  
46 encourage healthy behaviour.

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48 The TTC programme will be delivered on restricted password-protected website that allows  
49 the team to track usage. The TTC programme is set up in a modular fashion; participants work  
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3 through over a 15-week period at their own pace. Adolescents will be encouraged to log onto  
4 the website and complete one module per week. However, website activity will be flexible, and  
5 adolescents will be able to catch up missed modules (e.g. due to feeling unwell, exams, holidays  
6 etc.). A 91% (20/22) compliance was achieved in adolescents with JIA within the experimental  
7 group in the pilot RCT of the original TTC.<sup>6</sup> Consequently, for both TTC alone and integrated  
8 iP2P-TTC groups, data from participants completing at least 70% of the TTC programme will  
9 be considered valid for analyses.

- 15 ● *iP2P -TTC*

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17 As well as access to TTC each participant will be matched with a peer mentor. Mentors  
18 identified by HCP or the support groups (AI and iCAN) will have undergone 2 days training  
19 and Gardaí vetting prior to the programme. They will have SKYPE calls with their mentees for  
20 up to an hour every week. There will be flexibility in number of sessions a dyad will have (in  
21 Canadian pilot RCT males preferred fewer sessions).<sup>11</sup> However, we will advise weekly  
22 contact. The aim will be for a maximum of 12 calls within a 15-week period.

### 29 **Sample Size and Power Estimations.**

30 ***Pilot RCT:*** It is suggested that between 20 and 30 participants be recruited per group for pilot  
31 studies to examine overall feasibility and for development of estimates (e.g. variance) to  
32 compute power for a larger trial.<sup>15,16</sup> Therefore, we will recruit a total of 60 12-18-year-old  
33 participants (20 in each arm) and their primary caregivers.

34 ***Mentors for iP2P:*** At least 5 17-26-year-olds – will complete a previously validated 2-day  
35 training course (organised in collaboration between co-applicants, Drs. Stinson and Kohut and  
36 collaborators AI and iCAN), and supported throughout the duration of the study (e.g.  
37 consultations with research staff, additional training in mentorship skills if needed).

38 ***Young Person Advisory Panel:*** 5 12-20-year-olds will receive a day of training in research  
39 methods and exploration of their role as a team of experts in the study, and meet, both face-to-  
40 face and via Zoom, regularly over the course of the study. Our commitment to PPI, is based  
41 on ensuring our research results do enhance peoples' lives. So following the needs assessment  
42 with all the stakeholders, it was vital to ensure that teens with JIA and their families retained a  
43 voice in the development of all materials and rollout of the pilot RCT.

### 54 **Study Monitoring Procedures**

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56 In addition to the input from the YPAP, 'Lending an Ear' will have monthly meetings between  
57 all co-applicants and collaborators to ensure their expertise continues to inform challenge  
58 resolutions and progression.  
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## Measures

### (A) *Feasibility Outcomes:*

1. *Participant accrual and dropout rates* will be centrally tracked on-line by postdoctoral researcher and Research Assistant (RA).

2. *Fidelity:* Any issues or difficulties encountered during implementation of interventions, control strategy, or outcome measures will be tracked throughout the study.

3. *Acceptability and Satisfaction* with interventions:

- Post-treatment, adolescents with JIA and their parents in the TTC and iP2P-TTC intervention groups will rate acceptability of and satisfaction with the intervention on-line and through interviews (see below).
- Satisfaction with TTC and the integrated iP2P-TTC programme will also be captured using semi-structured interviews at study completion with 4-6 adolescent-parent dyads (chosen via random numbers list) who were randomised to the groups. Broader assessment of engagement (e.g., most helpful aspects, enjoyment, how tailoring was done) will be part of the semi-structured interviews.
- All participants randomised to the integrated iP2P-TTC will also be given a measure of mentor quality (Mentor Behaviour Scale) immediately following completion, to rate the quality of their received mentorship.
- Mentors will complete measures to assess their views on the iP2P training and be invited to:
  - Individual semi-structured telephone interviews conducted before they commence the mentoring programme (to gauge their expectations)
  - Ecological Momentary Assessment (EMA) methodology used throughout the mentoring programme. Mentors will be asked to complete a brief online open-ended questionnaire immediately after *each* Skype call with a mentee.
  - Individual 'data-prompted' interviews conducted face-to-face once the mentoring programme is complete.

4. *Engagement with interventions:*

- Google Analytics will be used to track patterns of website programme usage by adolescents with JIA and parents (e.g., which TTC modules have been accessed and in what order) in the TTC alone group.

- For participants in the integrated iP2P-TTC intervention the order and amount of used TTC modules, number of calls with mentor, length of calls and discussed topics will be tracked.
- In addition, Medical Issues, Exercise, Pain and Social Support Questionnaire (MEPS)<sup>17</sup> questionnaire (see effectiveness outcomes) will provide information on improved knowledge.

### 5. Tailoring:

To evaluate whether the iP2P component facilitates tailoring of the intervention to the needs of each teen, we will track for both intervention groups which modules they have visited and in which order. In addition, during the semi-structured interviews with mentors and mentees we will ask more details on how exactly this tailoring took place.

### **(B) Effectiveness Outcomes:**

*Adolescent will complete measures on-line evaluating:*

- Self-management (TRANSITION-Q)<sup>18</sup> 3 point scale, 14 items.
- HRQL (PedsQL Arthritis Module)<sup>19</sup> 5-point scale, 5 areas: Problem with Pain & Hurt (4 items), Problems with Daily Activities (5 items).
- Pain (PROMIS Pediatric Profile Pain Intensity and Interference scales)<sup>20</sup> 5-point scale, (8 items).
- Revised Children's Anxiety and Depression Scale (RCADS)<sup>21, 22</sup> - 25 items, with subscale scores for depression and anxiety as well as an overall internalising score.
- Disease knowledge (MEPS)<sup>17</sup> 10 point scale, 4 areas: Medical Issues (9 items), Exercise (4 items), Pain (6 items) Social Support (4 items)
- Self-efficacy (Children's Arthritis Self-Efficacy; CASE)<sup>23</sup> 5-point scale, (11 items)
- Perceived social support (PROMIS Paediatric Profile Peer Relationship Scale).<sup>24</sup> Short form 5 point scale, (8 items)
- Health Services Use and Out-of-Pocket Expense Diary-Youth Version<sup>25</sup> 10 different areas: Extracurricular activities (2 items), Academic activities (6 items) Loss of time (5 items), Contact with medical doctor (5 items), Allied health professionals and social service providers (2 Items), Emergency room visits (7 items), Hospital admissions (3 items), Medication (2 items), Medical devices (2 items), Parent loss of time from work (pain or unpaid) (16 items). Measure was adapted from health economist's thesis project.

*Parents will complete measures on-line assessing adolescents:*

- HRQL (PedsQL Arthritis Module).<sup>19</sup>
- Adherence (Adherence report questionnaire; PARQ)<sup>26</sup> 1-7 measures, scale of 10
- Medical issues (Medical Issues Questionnaire)<sup>17</sup> (9 items).
- Self-efficacy (Parent Arthritis Self-Efficacy; PASE)<sup>23</sup> 14 measures, 0-7 point scale from very uncertain to certain.

*Mentors will complete in relation to their own abilities:*

- Ability to Participate in Social Roles and Activities – PROMIS Short Form 8a - 10 point scale, (8 items); Exercise regularly Scale (3 items); Get information about disease (1 item); Obtain help from community, family, friends (4 items); Communicate with Physician (3 items); Manage disease in General (5 items); Do chores (3 items); Social/recreational Activities (2 items); manage symptoms (5 items); Manage shortness of breath (1 item); Control/manage depression (6 items).
- Chronic Disease Self-Efficacy Scale, 5 point scale, 10 areas.
- PROMIS–29 Profile v2.0.<sup>20</sup> 5 point scale 8 areas: Physical function (4 items), anxiety (4 items), Depression (4 items), fatigue (4 items), sleep disturbance (4 items), ability to participate in social roles and activities (4 items), Pain interference (4 items), Pain intensity on a scale of 1 – 10 (1 item).
- iPeer2Peer Mentor Training Evaluation 5 point scale, 10 items<sup>11</sup>
- Post-intervention Semi-structured Focus Group to explore their perspectives on how well the programme worked for the mentees and themselves.

*In addition to completing effectiveness outcome measures of TTC, mentees will also complete:*

- Mentor Behaviour Scale - 5 point scale of 4 areas: Structure (8 items), Engagement (2 items), Autonomy support (2 items), and Competency Support (3 items)<sup>27</sup>

All measures have evidence of reliability and validity in samples of adolescents with JIA.

## **Background measures**

For descriptive purposes and to obtain information on potential moderators of the strength of observed treatment effects, the following variables will be assessed at baseline:

- Adolescent and parent socio-demographic and JIA-related characteristics. Because this intervention is designed to be an adjunct to usual management approaches for JIA,



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3 participants will not be excluded if they are receiving common medical and physically  
4 based therapies. Information will be collected at each outcome measurement time point  
5 on whether participants in any group used or sought out any adjunct therapies (e.g.  
6 medications, physical, psychological and complementary/alternative therapies), social  
7 support (e.g. Facebook or Instant Messaging), disease specific information or  
8 attendance at a support group camp during the study period, to determine their extent  
9 of use.

- 15 ● Access, use, and comfort level with computers and the Internet (as expressed by  
16 themselves).
- 17 ● Expectation about treatment effectiveness from adolescents and parents (using  
18 numerical rating scale - 0='don't think it will help at all' to 10='think it will help a lot').  
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### 24 **Retention and Adherence**

25 Adolescents will be encouraged to log onto the website once per week for 12 weeks and  
26 complete one module per week.

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28 If a mentor/mentee dyad has not had a call within 2 weeks but has not indicated to the RA that  
29 they have terminated the programme, the RA will contact the participant to determine interest  
30 in continuing versus terminating their involvement or if they prefer to continue with just TTC  
31 programme. If they have decided to end the programme they will be asked to fill out outcome  
32 measures. If scheduled calls are missed, participants will receive reminders by the mentor  
33 and/or the RA via email, text, or phone. We will control for the number of Skype calls made in  
34 the analyses.  
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41 Characteristics of adherent versus non-adherent participants will be examined for systematic  
42 differences; when found, analyses will be conducted to determine effect on outcomes.  
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### 45 ***Losses to Follow-up***

46 Every effort will be made to retain participants in the study groups and to obtain post-treatment  
47 measures on all who enrolled. We will ask for multiple phone numbers (home, mobile phone)  
48 and/or email addresses, which will aid follow-up. To minimize losses to follow-up, the RA may  
49 make calls, texts and emails to remind participants of timing of various online assessments.  
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### 54 **Data Analysis**

55 All semi-structured interviews will be audio-taped and transcribed verbatim to determine  
56 satisfaction with the Irish TTC or TTC + iP2P programme.<sup>6</sup> The transcribed data will be  
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3 managed using NVivo 11 computer software programme, which allows for online coding and  
4 annotation of text. We will use content analyses as outlined by Elo and Kygnäs, (2008).<sup>28</sup>

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6 Quantitative data will be analysed using SPSS version 21. Descriptive statistics will be used to  
7 describe sample characteristics at baseline. Rates of accrual drop out, compliance, and missing  
8 data with 95% confidence intervals will be calculated. For continuous outcomes, the normality  
9 of the data will be assessed using histograms and normal probability plots. If assumptions are  
10 met, continuous outcomes will be analysed using linear mixed modelling to assess effect over  
11 time. If the data is not normally distributed, non-parametric equivalents will be used. For binary  
12 outcomes, a logistic regression analysis will be conducted.

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14 To inform sample size calculations and data analysis for a larger trial, data will be analysed as  
15 in a larger study, and estimates of variance and correlation (i.e., intra-cluster correlation within  
16 site) on physical (pain, fatigue) and emotional (anxiety, depression) symptoms, perceived  
17 social support, self- efficacy, adherence, knowledge, and HRQL will all be estimated. Analysis  
18 will be conducted using an intent-to-treat approach. If assumptions for parametric statistics are  
19 met, linear mixed models will be used to test intervention effects on outcomes using an analysis  
20 of covariance approach with post-treatment measures compared between groups using baseline  
21 scores as covariates. To control for type 1 error rate, Holm's Sequential correction will be  
22 applied. We will use the CONSORT<sup>29</sup> reporting guidelines to report this trial.

23  
24 Cost effectiveness and cost utility analyses will be conducted using both a healthcare system  
25 and societal perspective. Cost effectiveness and cost utility will be expressed as incremental  
26 cost effectiveness ratios (ICERs),<sup>30</sup> calculated by dividing the incremental costs between  
27 treatment arms by the incremental change in utility scores, measured as HRQL using the  
28 PedsQL. Multiple ICERS will be calculated comparing each of the three study groups in a  
29 pairwise fashion for both the cost effectiveness and cost utility analyses. Extensive  
30 deterministic and probabilistic sensitivity analysis will be performed to evaluate the robustness  
31 of the results. A 95% confidence interval for incremental costs, incremental effects, and the  
32 ICER will be calculated from study data using bootstrapping.

### 33 34 35 **Data monitoring and management**

36  
37 This study will collect non-identifying, minimally invasive information, which is not expected  
38 to cause any level of distress to participants. All data will be collected electronically and stored  
39 securely at the Centre for Pain Research on password-protected databases that can only be  
40 accessed by the research team.  
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3 Should any participant - parent, adolescent or young adult - indicate at any point during the  
4 study that they no longer wish to participate, that decision will be respected. If they would like  
5 to have their data up to that point destroyed or not used in the final analyses, they can inform  
6 the researcher of their wishes and their data will be confidentially shredded.  
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10 If an adolescent is found to be at risk of becoming distressed or not taking their meds,  
11 appropriate methods will be taken to inform those in positions of authority. The guidelines of  
12 the Child Protection Policy outlined by the respective hospital where the adolescent is being  
13 treated will be followed to ensure that they are fully supported throughout the project in relation  
14 to any issues that may arise. If an adolescent is considered to be at risk during the course of the  
15 project, a Senior Clinical Psychologist will be contacted by the researchers to provide  
16 appropriate guidance and consultation if necessary.  
17  
18

19 In accordance with the Ethical Guidance for research with children, all members of the research  
20 team will be Garda vetted and employment checks will be carried out.  
21  
22

23 All members of the research team will be trained and have access to relevant expertise in  
24 relation to child protection issues. All those researchers having face-to-face contact with the  
25 adolescents will have taken part in HSE Child First training.  
26  
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28 Additionally, written consent and assent will be obtained from all participating adolescents,  
29 their parents and the young adult mentors. During the consent process, the study procedures  
30 will be described in detail to both parents and adolescents, giving each individual time to read  
31 the information and the opportunity to ask questions. Adolescents and parents will also be  
32 advised that they are able to stop their participation at any time.  
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## 41 **Dissemination**

42 We will use both integrative and end-of-project knowledge exchange approaches to  
43 disseminate the findings to the public, patients with JIA and their families, support  
44 organisations, researchers and clinicians.  
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47 *Approach 1 will include:*

48 (a) Involving key stakeholders in all stages of the research process from the outset. Key  
49 stakeholders include adolescents with JIA (represented by the YPAP, patient organisations  
50 (e.g., AI, and iCAN), and clinicians).  
51  
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53 (b) Presentation of research findings by the PI and co-applicants at National, European and  
54 International conferences, plus published in leading paediatric or rheumatology journals to  
55 target all practicing health care professionals.  
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58 (c) Other strategies will include a 1-page report and YouTube video that will be:  
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- 3 1. Distributed to rheumatology health care professionals and patient groups across
- 4 Ireland,
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- 6 2. Included in media releases and posting/links on key websites (e.g.,
- 7 <http://www.juvenilearthritis.ie>) and social media,
- 8
- 9
- 10 3. Sent to all participants at the end of the project to inform them of the findings,
- 11
- 12 4. Included in conference presentations, which will be co-presented by researchers and
- 13 stakeholders (e.g., adolescents with JIA, Arthritis Ireland or iCAN representative)
- 14 where possible.
- 15
- 16

17 *Approach 2 will involve:* launching an interactive Internet conduit (“Irish Teens Taking  
18 Charge: Managing Arthritis Online” and peer mentoring) at the end of the project, if found to  
19 be effective, to share knowledge with users, predominately adolescents with JIA and their  
20 families, as well as other web audiences (e.g., peers, teachers, and health professionals).

21 This mode of communication can provide an effective tool to help in the collection, processing  
22 and targeted distribution of information about JIA research to benefit patients and their  
23 families, clinicians, researchers, administrators, health care policy makers, school  
24 administrations and the public.  
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#### 34 **Acknowledgements:**

35 All our collaborators and funders.

36 iCAN, Arthritis Ireland, all the families and HCP who are working with us on this project  
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43 Children’s Hospital (NCHF), grant number - NCHF-2017-003.  
44  
45  
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48

#### 49 **Conflict of interest:**

50 There are no conflicts of interest

#### 51 **Authors Statement:**

52 Dr. Siobhan O’Higgins

- 53
- 54
- 55
- 56 • Successfully applied for the ethics in both university and hospital, recruited and
- 57 trained both YPAPA and Mentors, devised recruitment posters, parents invite letter,
- 58
- 59
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4 consent and assent forms. Liaised with HCP and families. Devised the lay out of the  
5 measures and the survey for all participants. Tested same and made amendments.

- 6  
7 • Wrote the paper and the protocol. Revised it critically for important intellectual  
8 content  
9  
10 • Approved final version  
11  
12 • Agrees to be accountable for all aspects of the work.

13  
14 Professor Jennifer Stinson

- 15 • Designed and rolled out Canadian TTC and Peer2Peer. Oversaw all adaptations to the  
16 text and videos. Liaised with all HCP and families.  
17  
18 • Helped to draft the paper and the protocol and revised it critically for important  
19 intellectual content  
20  
21 • Gave final approval of the version published  
22  
23 • Agrees to be accountable for all aspects of the work  
24

25 Dr. Sarah Aloha Kohut

- 26 • Designed and rolled out Canadian iP2P and oversaw adaptations to the training and  
27 planning of the mentoring aspect of the study. Helped design the measures for the  
28 whole study to ensure questionnaire not too onerous for participants  
29  
30 • Revised the paper critically for important intellectual content.  
31  
32 • Gave final approval of the version published  
33  
34 • Agrees to be accountable for all aspects of the work.  
35

36 Dr. Line Caes

- 37 • Involved with the design of the work, helped revise and then deliver the adapted  
38 training for the mentors.  
39  
40 • Supported the drafting of the paper and also revised it critically for important  
41 intellectual content  
42  
43 • Gave final approval of the version published  
44  
45 • Agrees to be accountable for all aspects of the work.  
46  
47

48 Dr. Caroline Heary

- 49 • Involved in the design of the pilot RCT and selection of appropriate measures.  
50  
51 • Revised the paper critically for important intellectual content.  
52  
53 • Gave final approval of the version published  
54  
55 • Agrees to be accountable for all aspects of the work.  
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57 Professor Brian McGuire  
58  
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3  
4 • Designed the whole study, oversaw all engagement with participants and  
5 stakeholders, advised on selection of appropriate measures. Has final say on all  
6 aspects of the study as P.I.  
7  
8 • Revised the paper critically for important intellectual content.  
9  
10 • Gave final approval of the version published  
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12 • Agrees to be accountable for all aspects of the work.  
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### 14 **Trial Registration**

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16 Registration number: ISRCTN13535901.  
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## References

1. Arthritis Ireland (2017). Retrieved from: <http://www.juvenilearthritis.ie>
2. Sawyer, M. G., Whitham, J. N., Robertson, D. M., Taplin, J. E., Varni, J. W., & Baghurst, P. A. (2004). The relationship between health-related quality of life, pain and coping strategies in juvenile idiopathic arthritis. *Rheumatology*, *43*(3), 325-330.
3. Stinson, J., Kohut, S. A., Forgeron, P., Amaria, K., Bell, M., Kaufman, M. & Spiegel, L. (2016). The iPeer2Peer program: a pilot randomized controlled trial in adolescents with juvenile idiopathic arthritis. *Pediatric Rheumatology*, *14*(1), 48.
4. Simons, L.E., Logan, D.E., Chastain, L. & Cerullo, M. (2010). Engagement in Multidisciplinary interventions for pediatric chronic pain: parental expectations, barriers, and child outcomes. *Clinical Journal of Pain*, *26*, 291–299.
5. Stinson, J., McGrath, P., Hodnett, E., Feldman, B., Duffy, C., Huber, A. & Campillo, S. (2010). Usability testing of an online self-management program for adolescents with juvenile idiopathic arthritis. *Journal of Medical Internet Research*, *12*(3), e30.
6. Stinson, J. N., McGrath, P. J., Hodnett, E. D., Feldman, B. M., Duffy, C. M., Huber, A. M. & Campillo, S. (2010). An internet-based self-management program with telephone support for adolescents with arthritis: a pilot randomized controlled trial. *The Journal of Rheumatology*, *37*(9), 1944-1952.
7. Dennis, C.L. (2003). Peer support within a health care context: A concept analysis. *International Journal of Nursing Studies*, *40*(3), 321–332.
8. Kohut, S. & Stinson, J. (2014). Systematic review of peer support interventions for adolescents with chronic illness: A narrative analysis. *International Journal of Child and Adolescent Health*, *7*, 183-197.
9. Sandhu, S., Veinot, P., Embuldeniya, G., Brooks, S., Sale, J., Huang, S. & Bell, M. J. (2013). Peer-to-peer mentoring for individuals with early inflammatory arthritis: feasibility pilot. *BMJ open*, *3*(3), e002267.
10. Zelikovsky, N. & Petrongolo, J. (2013). Utilizing peer mentors for adolescents with chronic health conditions: Potential benefits and complications. *Pediatric transplantation*, *17*(7), 589-591.
11. Kohut, S. A., Stinson, J. N., Ruskin, D., Forgeron, P., Harris, L., van Wyk, M. & Campbell, F. (2016). iPeer2Peer program: a pilot feasibility study in adolescents with chronic pain. *Pain*, *157*(5), 1146-1155.
12. Ford P. (2017). The app route to patient engagement. *HIMSS Europe*, *5*(3),

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3 16-17  
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- 5 13. O’Sullivan, G., O’Higgins, S., Caes L., Saetes, S., McGuire, B.E., & Stinson, J., (accepted  
6 October 2018). Self-management needs of Irish adolescents with Juvenile Idiopathic Arthritis  
7 (JIA): how can a Canadian web-based programme meet these needs? *Journal of Pediatric*  
8 *Rheumatology*.  
9  
10  
11  
12 14. Stinson, J & O’Higgins S., (2019) Pushing the frontier of Digital Health to  
13 transform Paediatric self- management (Power point presentation to Health  
14 Care Providers in Temple Street Children’s Hospital, Dublin).  
15  
16 15. Hertzog, M.A. (2008). Considerations in determining sample size for pilot  
17 studies. *Research in Nursing & Health*, 31, 180–191.  
18  
19 16. Arain, M., Campbell, M. J., Cooper, C. L. & Lancaster, G. A. (2010). What is a pilot  
20 or feasibility study? A review of current practice and editorial policy. *BMC medical*  
21 *research methodology*, 10(1), 67.  
22  
23 17. André M, Hedengren E, Hagelberg S, Stenström CH. Perceived ability to manage  
24 juvenile chronic arthritis among adolescents and parents: development of a  
25 questionnaire to assess medical issues, exercise, pain, and social support. *Arthritis Care*  
26 *Res.* 1999;12(4):229-237.  
27  
28 18. Klassen AF, Grant C, Barr R, et al. Development and validation of a generic scale for  
29 use in transition programmes to measure self-management skills in adolescents with  
30 chronic health conditions: the TRANSITION-Q. *Child Care Health Dev.*  
31 2014;41(4):547-558.  
32  
33 19. Varni, W. J., Seid, M., Smith Knight, T., Burwinkle, T., Brown, J., Szer, I., The  
34 PedsQL™ in pediatric rheumatology: Reliability, validity, and responsiveness of the  
35 Pediatric Quality of Life Inventory™ Generic Core Scales and Rheumatology Module.  
36 *Arthritis & Rheumatology* 2002: 46(3):714-25.  
37  
38 20. Jacobson, C.J., Kashikar-Zuck, S., Farrell, J., Barnett, K., Goldschneider, K., Dampier,  
39 C., Cunningham, N., Crosby, L. & DeWitt, E.M. (2015). Qualitative evaluation of  
40 pediatric pain, behavior, quality and intensity item candidates and the PROMIS pain  
41 domain framework in children with chronic pain. *J Pain.* 16(12), 1243-55.  
42  
43 21. Chorpita, B. F., Yim, L., Moffitt, C., Umemoto, L. A., Francis, S. E., Assessment of  
44 symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and  
45 depression scale. *Behaviour Research and Therapy.* 2000; 38(8), 835-855.  
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22. Chorpita, B. F., Ebesutani, C., Spence, S., Revised Children's Anxiety and Depression Scale, User Guide. 2015 downloaded from [www.childfirst.ucla.edu](http://www.childfirst.ucla.edu) 22.04.2018.
  23. Brady Teresa J. (2011) Measures of self-efficacy: Arthritis Self-Efficacy Scale (ASES), Arthritis Self-Efficacy Scale-8 Item (ASES-8), Children's Arthritis Self-Efficacy Scale (CASE), Chronic Disease Self-Efficacy Scale (CDSSES), Parent's Arthritis Self-Efficacy Scale (PASE), and Rheumatoid Arthritis Self-Efficacy Scale (RASE). *Arthritis Care & Research*. 2011; 63 (S11): S473-
  24. DeWalt DA, Thissen D, Stucky BD, Langer MM. PROMIS pediatric peer relationships scale: Development of a peer relationships item bank as part of social health measurement. *Health Psychology*. 2013; 32(10):1093-1103.
  25. Moretti ME A cost-effectiveness analysis of maternal genotyping to guide treatment for postpartum pain and avert infant adverse events. [PhD Dissertation] Toronto, Canada: Institute of Health Policy Management and Evaluation, University of Toronto; 2014.
  26. De Civita, M., Dobkin, P., Ehrmann-Feldman, D., Karp, I., Duffy, C. Development and Preliminary Reproducibility and Validity of the Parent Adherence Report Questionnaire: A Measure of Adherence in Juvenile Idiopathic Arthritis. *Journal of Clinical Psychology in Medical Settings*. 2005; 12(1): 1-12.
  27. Brodeur P, Larose S, Tarabulsky G, Feng B, Forget-Dubois N. Development and Construct Validation of the Mentor Behavior Scale. *Mentoring & Tutoring: Partnership in Learning*. 2015;23(1):54-75.
  28. Elo, S. & Kyngäs, H. (2008). The qualitative content analysis process. *Journal of Advanced Nursing*, 62(1), 107-115.
  29. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.
  30. Bensink, M., Wootton, R., Irving, H., Hallahan, A., Theodoros, D., Russell, T. & Barnett, A. G. (2007). Investigating the cost-effectiveness of video telephone based support for newly diagnosed paediatric oncology patients and their families: design of a randomised controlled trial. *BMC health services research*, 7(1), 38.

Development of pilot RCT and future for full RCT of Irish Teens Taking Charge and iPeer2Peer

Figure 1

## Steps in Development, Evaluation and Future plans



### PHASE 1

➤ Needs assessment + what changes needed to make TTC relatable to Irish context (HCP, teens and parents)



### PHASE 2

➤ Irish TTC usability tested (HCP, teens and parents)  
➤ Mentors trained and ready for SKYPE mentoring



### PHASE 3

➤ Feasibility and preliminary outcome testing (pilot RCT) with 3 arms - Control, TTC, TTC+iP2P



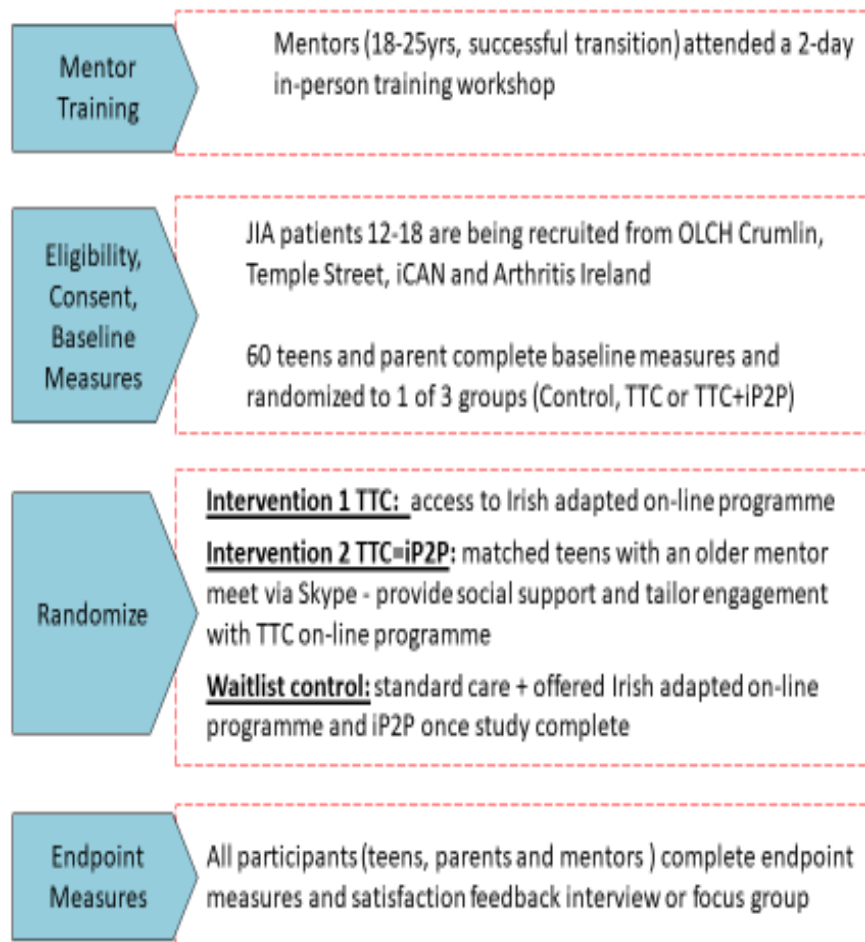
### PHASE 4 – in the future

➤ Multi-centred RCT

W Only

### Schema of pilot RCT of TTC with iPeer2Peer

Figure 2



only



## CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-5
	2b	Specific objectives or research questions for pilot trial	5
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	9-12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	
Sample size	7a	Rationale for numbers in the pilot trial	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7

1	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
2	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
3		11b	If relevant, description of the similarity of interventions	7-8
4	Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9-12
5	<b>Results</b>			
6	Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	n/a
7		13b	For each group, losses and exclusions after randomisation, together with reasons	n/a
8	Recruitment	14a	Dates defining the periods of recruitment and follow-up	n/a
9		14b	Why the pilot trial ended or was stopped	n/a
10	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	n/a
11	Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	n/a
12	Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	n/a
13	Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
14	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
15		19a	If relevant, other important unintended consequences	
16	<b>Discussion</b>			
17	Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	n/a
18	Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	n/a
19	Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	n/a
20		22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	n/a
21	<b>Other information</b>			
22	Registration	23	Registration number for pilot trial and name of trial registry	3,17
23	Protocol	24	Where the pilot trial protocol can be accessed, if available	
24	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15
25		26	Ethical approval or approval by research review committee, confirmed with reference number	1

1 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

2 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important  
3 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological  
4 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).  
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For peer review only

# BMJ Open

## LENDING AN EAR: IPEER2PEER PLUS TEENS TAKING CHARGE ONLINE SELF-MANAGEMENT TO EMPOWER ADOLESCENTS WITH ARTHRITIS IN IRELAND. PROTOCOL FOR A PILOT RCT.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-027952.R2
Article Type:	Protocol
Date Submitted by the Author:	12-Jul-2019
Complete List of Authors:	O'Higgins, Siobhan; National University of Ireland, Galway, Centre for Pain Research, School of Psychology Stinson, Jennifer; University of Toronto, Faculty of Nursing ; Hospital for Sick Children Ahola Kohut, Sara; University of Toronto, Faculty of Nursing ; Hospital for Sick Children, Medical Psychiatry Alliance Caes, Line; University of Stirling , Division of Psychology, Faculty of Natural Sciences Heary, Caroline; National University of Ireland, School of Psychology McGuire, Brian; National University of Ireland, Galway, Ireland, School of Psychology & Centre for Pain Research
<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Paediatrics
Keywords:	Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, Information technology < BIOTECHNOLOGY & BIOINFORMATICS, Paediatric rheumatology < PAEDIATRICS, Juvenile Rheumatoid Arthritis, Adolescent Stakeholder involvement, Quality of life, Self-care, Online interventions

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Manuscripts



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3 **LENDING AN EAR: IPEER2PEER PLUS TEENS TAKING CHARGE ONLINE**  
4 **SELF-MANAGEMENT TO EMPOWER ADOLESCENTS WITH ARTHRITIS IN**  
5 **IRELAND. PROTOCOL FOR A PILOT RCT.**  
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41 **Keywords:**

42 **Juvenile Rheumatoid Arthritis, Adolescent Stakeholder involvement, Quality of life,**  
43 **Self-care, Online interventions**  
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48 **Word count: 4391**  
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## Abstract

### Introduction:

Juvenile Idiopathic Arthritis (JIA) negatively affects adolescents' everyday activities. To address the need for innovative, effective, convenient, low-cost psychosocial self-management programmes, we developed an Irish version of Canadian Teens Taking Charge (TTC) and integrated it with skype-based peer support iPeer2Peer (iP2P).

### Objectives:

To explore the feasibility and preliminary outcome impact (effectiveness) of an integrated iP2P and Irish TTC, via 3- arm (treatment as usual, TTC and iP2P-TTC) pilot RCT; and determine feasibility and sample size for a full RCT. To ensure active involvement of adolescents with JIA via a Young Person Advisory Panel (YPAP) and examine how participants experienced the study. Finally, to see if TTC and iP2P with TTC reduce costs for families.

### Methods and analysis:

Recruitment of 60 families will be on-going until July 2019, via HCP and support groups. Analysis will consist of single-blinded (outcome assessment), 3-arm pilot RCT, using on-line questionnaires, with assessments at baseline (T1), after intervention (T2), and 3 months post-intervention (T3). The primary outcomes on feasibility with comparisons of TTC and iP2P-TTC on fidelity, acceptability and satisfaction, engagement, and degrees of tailoring. The secondary outcomes will be self-management and self-efficacy and a range of health-related quality of life factors, pain indicators, and costs.

Participants from the intervention groups will be invited to share their perspectives on the process in semi-structured interviews. Quantitative data will be analysed using SPSS version 21 and the audio-taped and transcribed qualitative data will be analysed using qualitative content analysis.

Ethical approval: Research Ethics Committees - National University of Ireland, Galway and Our Lady's Children's Hospital (OLCH), Crumlin, and Temple Street Children's Hospital, Dublin.

Dissemination: via journal articles, conference presentations, co-delivered by key stakeholders when possible, launch of accessible, effective and sustainable Internet self-management and peer support for Irish adolescents with JIA.

RCT Registration number: ISRCTN13535901

## Article Summary - Strengths and limitations

- This study follows from an in-depth qualitative exploration of the need and desire among stakeholders for an on-line support programme.
- The needs analysis offered suggestions on how to adapt the Canadian programme to ensure that the programme offered relevant information to the Irish context; these changes have been achieved.
- Canadian TTC is known to improve the lives of teens with JIA and their families, this study builds on that success by adding extra elements of tailoring and sustainability with the iP2P peer mentoring.
- Sustainability of the integrated programme, if found to be effective, is ensured due to: on-going collaboration with all stakeholders; Arthritis Ireland (a non-profit support service for people with Arthritis) taking over the peer mentoring element of the intervention, with on-going training and support for mentors, and; TTC will be up-dated biannually by About Kids Health in Toronto and Health Care Professionals in Ireland.
- Recruitment of sufficient teens and their families for the RCT may be difficult, hence active involvement of all stakeholders and the YPAP will be crucial to reach our target sample size.

## Introduction

JIA is the most common childhood rheumatic disease. In Ireland 1,200 children live with JIA, with over 100 children newly diagnosed annually.<sup>1</sup> Children and adolescents commonly experience a myriad of physical and emotional symptoms that restrict physical and social interactions and negatively impact their health-related quality of life (HRQL).<sup>2, 3</sup> There is no cure, the disease course can be unpredictable, and HRQL deteriorates with increased disease severity, active joint counts, pain, and degree of disability.<sup>2, 3</sup> The Irish rheumatologist to patient ratio for children with arthritis is second lowest in Europe, with waiting lists of up to 2 years; access to psychological support is equally limited. In addition, transition to adult services is scheduled by age 16 years, rather than 18 as in Canada. So, although cognitive-behavioural therapy (CBT) interventions can lead to improvement in pain and HRQL,<sup>4</sup> most teens with JIA in Ireland will not receive these interventions although eventually they may avail of them through the adult rheumatology services. Hence, the need for supports to develop self-management skills for adolescents with JIA. Using the internet is a possible solution to address

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2  
3 the gap between need, availability and access to effective treatments. Online interventions are  
4 scalable and accessible in the moment, 24 hours a day, and do not need therapist involvement.  
5 Prior to this study, our Canadian colleagues evaluated the two programmes in the present study  
6 separately. Stinson and colleagues developed and tested the usability, feasibility and  
7 effectiveness of Teens Taking Charge (TTC), an online self-management programme  
8 consisting of 12 modules for teens and 2 for parents, with telephone support from a health  
9 coach (trained, adult non-Health Care Professionals (HCP) without arthritis) for Canadian  
10 adolescents with JIA.<sup>3,5,6</sup> Significant improvements were found in disease-related knowledge,  
11 decreased pain and increased exercise adherence.<sup>6</sup> Peer support by another person with similar  
12 chronic illness is associated with improved health outcomes.<sup>7-10</sup> iPeer2Peer (iP2P), an online  
13 peer mentoring programme, was evaluated with adolescents with chronic pain, and found to  
14 improve acceptability of self-management and peer support treatments.<sup>11</sup> Although positively  
15 evaluated separately the two programmes have not be combined before.

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Localising available and effective programmes which meet the specific needs of patients is an important development strategy for facilitating timely availability of evidence-based programmes.<sup>12</sup> Hence we conducted an Irish qualitative needs assessment working with members (teens and parents) of two patient organisations: Arthritis Ireland (AI), and Irish Children's Arthritis Network (iCAN, a support group set up by a parent for other parents and teens with JIA); health care professionals from Our Lady's Children's Hospital (OLCH) Crumlin and other paediatric units. The interviews explored stakeholder perspectives on:

- Impact of JIA on adolescents and families
- Current Irish service provision
- The value and usability of Canadian "TTC: Managing Arthritis Online" and iP2P programmes

Lack of access to local multidisciplinary rheumatology teams was the main concern of all stakeholders. There was consensus that TTC would be a useful resource once TTC information was tailored to the Irish context and specific needs of each patient, and facilitated through peer mentoring.<sup>13</sup>

These views taken together, underpinned the critical need for accessible and effective interventions to assist Irish adolescents with JIA to find effective ways to self-manage symptoms and improve overall HRQL. iP2P mentoring combined with TTC also has the potential to reduce the burden on services, by providing information, support and empowerment tailored to the teens in- the- moment needs, reducing the need to contact HCP.

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3 Based on our qualitative need assessment, and through further consultations with HCP, support  
4 services A.I and iCAN, the 5 teens with JIA who make up our Young Person Advisory Panel  
5 (YPAP), and their parents, the Canadian TTC website's 3 components which are encapsulated  
6 within the 12 modules, have been culturally adapted:  
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- 10 1. Disease specific content (what is JIA, how is it diagnosed, how is it treated using  
11 pharmacological, physical and psychological strategies);  
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- 13 2. Developing self-management skills to live well with JIA (managing emotions, managing  
14 physical symptoms, healthy lifestyle, skills to move on to adult health care, education and  
15 vocational skills to manage JIA);  
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- 17 3. Social support (videos, and stories of hope).  
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20 The Irish TTC has videos of Irish teens with JIA and their parents and HCP talking about the  
21 different topics, integrated with videos of Canadians, throughout the 12 modules. The text has  
22 been adapted with relevant drugs, service and financial support offered in Ireland rather than  
23 those in Canada. This process has taken a year to achieve and Sick Kids Hospital adapted the  
24 on-line TTC to incorporate the changes that ensure the Irish TTC is acceptable and relevant  
25 to Irish families. The development of the pilot RCT can be seen in Figure 1.  
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31 This study will examine if greater reach and adoption of self-management and peer support  
32 programmes are achievable using novel information and communication technologies (i.e., e-  
33 Health), shown in Figures 2<sup>14</sup> and 3.  
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### 36 **Objectives:**

- 37 ● Explore feasibility and preliminary outcome impact (effectiveness) of an integrated iP2P  
38 and Irish TTC, via 3- arm (treatment as usual, TTC and iP2P-TTC) pilot RCT of "Teens  
39 Taking Charge: Managing Arthritis Online" to help adolescents with JIA improve their  
40 self-management skills, HRQL, disease knowledge, social support, self-efficacy, physical  
41 symptoms and emotional distress, compared to a treatment as usual control group.  
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- 43 ● Determine feasibility and sample size for a full RCT;  
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- 45 ● Ensure active involvement of adolescents with JIA throughout the study with creation and  
46 support of a Young Person Advisory Panel (YPAP), who communicate monthly with the  
47 research team via ZOOM calls and WhatsApp group messaging. They and their parents  
48 reviewed the videos and text of the Irish TTC, posters and all recruitment information sent  
49 out to parents and teens.  
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- 51 ● To examine how participants experienced the study  
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- 53 ● To see if TTC and iP2P and TTC reduce costs for families of teens with JIA.  
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## Hypotheses:

1. A feasible Internet self-management programme alongside a peer support intervention will provide Irish adolescents with JIA evidenced-based arthritis self-management and transitional care knowledge and skills; as well as the possibly of reducing HC costs for families.
2. The involvement of the YPAP, AI and iCAN will support a successful, sustainable and adolescent-appropriate launch of the adjusted Irish TTC and peer support programme.

## Methods and Analysis

### *Patient and Public Involvement*

Before designing the pilot RCT we worked with adolescents with JIA their parents and HCP to explore their experiences of living with JIA, levels of support and medications within the Irish system and explored whether interventions such as TTC and iP2P would be welcomed and useful to them.<sup>13</sup>

Once we knew that the interventions would be positively received and of use to our target population, we invited adolescents and their parents to be part of a Young Persons' Advisory Panel (YPAP) from the start of the research process.

All stakeholders were involved in the adaption of the on-line programme, recruitment of the mentors and trialling of the adapted on-line programme, design of recruitment posters and the measures for the on-line pre and post the intervention. Hosted by Limesurvey.

The YPAP met initially – courtesy of their parents bringing them to a central location - for a day's training. The group meet every month either via WhatsApp or scheduled ZOOM meetings, another face to face day is planned during school holidays.

See our dissemination plans for how study participants will be kept informed of the progress of the study and our results.

From the start of this process, stakeholders have reviewed several times the on-line intervention, and given feedback on how to ensure it is both acceptable and accessible to the Irish target population of teens with JIA and their parents.

### *Study design*

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3 A single-blinded (outcome assessment), pilot RCT design with three arms (20 teens in each) to  
4 test the feasibility and effectiveness of the Irish adapted TTC with and without integrated iP2P  
5 intervention for a 12-week period.  
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### 8 ***Participant Eligibility***

#### 9 *Inclusion criteria:*

- 10 • Adolescents between 12-18 years old
- 11 • Parental consent for teen to participate
- 12 • Adolescents diagnosed with and actively being treated for JIA
- 13 • Parent and adolescent both able to speak and read English
- 14 • Access to a computer, smartphone or tablet capable of using free Skype software
- 15 • Willing and able to complete online measures
- 16 • Adolescent eligible to participate without participation of a parent

#### 17 *Exclusion criteria*

- 18 • Major cognitive impairments – based on medical assessments
- 19 • Co-morbid medical or psychiatric illnesses which may impact on ability to understand  
20 and use web-based programmes – based on medical assessments
- 21 • Parents/caregivers not eligible to participate in the study without an adolescent.

### 22 ***Recruitment***

23 Three recruitment avenues:

- 24 i) All registered and eligible patients of OLCH Crumlin Paediatric Rheumatology programme  
25 will be sent an invitation to participate, by the HCP. Plus the research team will invite patients  
26 attending regularly scheduled clinic visits.
- 27 ii) Both AI and iCAN will be asked to inform their members of the study.
- 28 iii) The study will be advertised through various social media channels (Facebook, Twitter  
29 etc.).

30 For all routes of recruitment: once a parent emails or calls the Centre for Pain Research (CPR)  
31 more information this will be sent out by the RA, with consent and assent forms for both parents  
32 and adolescent.

33 It is not anticipated that the 3 processes will recruit sufficiently different types of teens –  
34 although those recruited by HCP may be those with a more recent diagnosis. Date of diagnosis  
35 will be noted in their demographic survey and on consent and assent forms for future reference.  
36 All potential participants will be contacted, consent and assent forms as well as detailed  
37 information emailed or sent to each family, to be returned signed prior to randomisation.

38 Recruitment will continue until end of July 2019.



### ***Randomisation***

When a participant agrees to take part in the trial, they will all complete on-line T1 measures and then be randomly assigned to one of the three arms using random permuted blocks to ensure balanced groups. Randomisation will be via a custom-written script, administered from a password-secured server, by the CPR's medical statistician. As such, researchers will not hold influence in the allocation process. Once assigned to a group the specific details for involvement over the next 12 weeks will be emailed to them.

### ***Description of study arms***

(a) Control group will receive usual healthcare appointments, medication and therapies, which may include physiotherapy, occupational therapy and talking with a psychologist (these are often organised by families rather than through the hospital).

(b) Experimental groups

- *For both intervention groups (TTC alone and iP2P-TTC)*

In addition to standard medical care, the two experimental groups will receive 12 modules of interactive multi-component self-guided online TTC intervention. There are also two modules specifically for parents/caregivers to help encourage healthy behaviour.

The TTC programme will be delivered on a restricted password-protected website allowing the team to track usage. TTC programme is set up in a modular fashion that participants work through over a 15-week period at their own pace. Adolescents will be encouraged to log onto the website and complete one module per week. However, website activity will be flexible, and adolescents will be able to catch up missed modules (e.g. due to feeling unwell, exams, holidays etc.). A 91% (20/22) compliance was achieved in the pilot RCT of the original TTC.<sup>6</sup> Consequently, for both TTC alone and integrated iP2P-TTC groups, data from participants completing at least 70% of the TTC programme will be considered valid for analyses.

- *iP2P -TTC*

As well as access to TTC each participant will be matched with a peer mentor. Mentors identified by HCP or the support groups (AI and iCAN) will have undergone 2 days training and Gardaí vetting. They will have SKYPE calls with their mentees for up to an hour every week. There will be flexibility in number of sessions a dyad will have (in Canadian pilot RCT males preferred fewer sessions).<sup>11</sup> However, we will advise weekly contact. The aim will be for a maximum of 12 calls within 15-weeks.

### **Sample Size and Power Estimations.**

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3 **Pilot RCT:** It is suggested that between 20 and 30 participants be recruited per group for pilot  
4 studies to examine overall feasibility and for development of estimates (e.g. variance) to  
5 compute power for a larger trial.<sup>15,16</sup> Therefore, we will recruit a total of 60 12-18-year-old  
6 participants (20 in each arm) and their primary caregivers.  
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10 **Mentors for iP2P:** At least 5 17-26-year-olds – will complete a previously validated 2-day  
11 training course (organised in collaboration between co-applicants, Drs. Stinson and Kohut and  
12 collaborators AI and iCAN), and supported throughout the duration of the study (e.g.  
13 consultations with research staff, additional training in mentorship skills if needed).  
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17 **Young Person Advisory Panel:** 5 12-20-year-olds following a day's training in research  
18 methods and exploration of their role as a team of experts, and meet, both face-to-face and via  
19 Zoom, regularly over the course of the study. Our commitment to PPI, is based on ensuring  
20 our research results do enhance peoples' lives. So, following the needs assessment with all the  
21 stakeholders, it is vital to ensure that teens with JIA and their families retain a voice in the  
22 development of all materials and rollout of the pilot RCT.  
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### 25 **Study Monitoring Procedures**

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27 In addition to the input from the YPAP, 'Lending an Ear' will have monthly meetings between  
28 all co-applicants and collaborators to ensure their expertise continues to inform challenge  
29 resolutions and progression.  
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### 34 **Measures**

#### 35 **(A) Feasibility Outcomes:**

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37 1. *Participant accrual and dropout rates* will be centrally tracked on-line by postdoctoral  
38 researcher and Research Assistant (RA).  
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41 2. *Fidelity:* Any issues or difficulties encountered during implementation of interventions,  
42 control strategy, or outcome measures will be tracked.  
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46 3. *Acceptability and Satisfaction* with interventions:  
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- 48 ● Post-treatment, adolescents with JIA and their parents in the TTC and iP2P-TTC  
49 intervention groups will rate acceptability of and satisfaction with the intervention on-  
50 line and through interviews (see below).  
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- 52 ● Satisfaction with TTC and the integrated iP2P-TTC programme will also be captured  
53 using semi-structured interviews at study completion with 4-6 adolescent-parent dyads  
54 (chosen via random numbers list). Broader assessment of engagement (e.g., most  
55 helpful aspects, enjoyment, how tailoring was done) will be part of the semi-structured  
56 interviews.  
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- All participants randomised to the integrated iP2P-TTC will also be given a measure of mentor quality (Mentor Behaviour Scale) immediately following completion.
- Mentors will complete measures to assess their views on the iP2P training and invited to:
  - Individual semi-structured telephone interviews conducted before they commence the mentoring programme (to gauge their expectations)
  - Ecological Momentary Assessment (EMA) methodology will be used throughout the mentoring programme. Mentors will be asked to complete a brief online open-ended questionnaire immediately after *each* mentee Skype call.
  - Individual ‘data-prompted’ interviews conducted face-to-face once the mentoring programme is complete.

#### 4. *Engagement with interventions:*

- Google Analytics will track patterns of website programme usage by adolescents with JIA and parents (e.g., which TTC modules have been accessed and in what order) in TTC group.
- For participants in the integrated iP2P-TTC intervention the order and amount of TTC modules used, number and length of calls with mentor, and discussed topics will be tracked.
- Medical Issues, Exercise, Pain and Social Support Questionnaire (MEPS)<sup>17</sup> questionnaire (see effectiveness outcomes) will provide information on improved knowledge.

#### 5. *Tailoring:*

To evaluate whether the iP2P component facilitates tailoring of the intervention to the needs of each teen, we will track for both intervention groups which modules they have visited and in which order. In addition, the semi-structured interviews with mentors and mentees will ask more details on how exactly this tailoring took place.

#### **(B) Effectiveness Outcomes:**

*Adolescent will complete measures on-line evaluating:*

- Self-management (TRANSITION-Q)<sup>18</sup> 3-point scale, 14 items.
- HRQL (PedsQL Arthritis Module)<sup>19</sup> 5-point scale, 5 areas: Problem with Pain & Hurt (4 items), Problems with Daily Activities (5 items).

- Pain (PROMIS Pediatric Profile Pain Intensity and Interference scales)<sup>20</sup> 5-point scale, (8 items).
- Revised Children's Anxiety and Depression Scale (RCADS) <sup>21, 22</sup> - 25 items, with subscale scores for depression and anxiety as well as an overall internalising score.
- Disease knowledge (MEPS)<sup>17</sup> 10-point scale, 4 areas: Medical Issues (9 items), Exercise (4 items), Pain (6 items) Social Support (4 items)
- Self-efficacy (Children's Arthritis Self-Efficacy; CASE) <sup>23</sup> 5-point scale, (11 items)
- Perceived social support (PROMIS Paediatric Profile Peer Relationship Scale).<sup>24</sup> Short form 5-point scale, (8 items)
- Health Services Use and Out-of-Pocket Expense Diary-Youth Version<sup>25</sup> 10 different areas: Extracurricular activities (2 items), Academic activities (6 items) Loss of time (5 items), Contact with medical doctor (5 items), Allied health professionals and social service providers (2 Items), Emergency room visits (7 items), Hospital admissions (3 items), Medication (2 items), Medical devices (2 items), Parent loss of time from work (pain or unpaid) (16 items). Measure was adapted from health economist's thesis project.

*Parents will complete on-line measures assessing adolescents:*

- HRQL (PedsQL Arthritis Module). <sup>19</sup>
- Adherence (Adherence report questionnaire; PARQ)<sup>26</sup> 1-7 measures, scale of 10
- Medical issues (Medical Issues Questionnaire)<sup>17</sup> (9 items).
- Self-efficacy (Parent Arthritis Self-Efficacy; PASE) <sup>23</sup> 14 measures, 0-7-point scale from very uncertain to certain.

*Mentors will complete in relation to their own abilities:*

- Ability to Participate in Social Roles and Activities – PROMIS Short Form 8a – 10-point scale, (8 items); Exercise regularly Scale (3 items); Get information about disease (1 item); Obtain help from community, family, friends (4 items); Communicate with Physician (3 items); Manage disease in General (5 items); Do chores (3 items); Social/recreational Activities (2 items); manage symptoms (5 items); Manage shortness of breath (1 item); Control/manage depression (6 items).
- Chronic Disease Self-Efficacy Scale, 5-point scale, 10 areas.

- PROMIS–29 Profile v2.0.<sup>20</sup> 5-point scale 8 areas: Physical function (4 items), anxiety (4 items), Depression (4 items), fatigue (4 items), sleep disturbance (4 items), ability to participate in social roles and activities (4 items), Pain interference (4 items), Pain intensity on a scale of 1 – 10 (1 item).
- iPeer2Peer Mentor Training Evaluation 5-point scale, 10 items <sup>11</sup>
- Post-intervention Semi-structured Focus Group to explore their perspectives on how well the programme worked for the mentees and themselves.

*In addition to completing effectiveness outcome measures of TTC, mentees will also complete:*

- Mentor Behaviour Scale - 5-point scale of 4 areas: Structure (8 items), Engagement (2 items), Autonomy support (2 items), and Competency Support (3 items) <sup>27</sup>

All measures have evidence of reliability and validity in samples of adolescents with JIA.

### **Background measures**

For descriptive purposes and to obtain information on potential moderators of the strength of observed treatment effects, the following variables will be assessed at baseline:

- Adolescent and parent socio-demographic and JIA-related characteristics. Because this intervention is designed to be an adjunct to usual management approaches for JIA, participants will not be excluded if they are receiving common medical and physically based therapies. Information will be collected at each outcome measurement time point on whether participants in any group used or sought out any adjunct therapies (e.g. medications, physical, psychological and complementary/alternative therapies), social support (e.g. Facebook or Instant Messaging), disease specific information or attendance at a support group camp during the study period, to determine their extent of use.
- Access, use, and comfort level with computers and the Internet (as expressed by themselves).
- Expectation about treatment effectiveness from adolescents and parents (using numerical rating scale - 0='don't think it will help at all' to 10='think it will help a lot').

### **Retention and Adherence**

Adolescents will be encouraged to log onto the website once per week for 12 weeks and complete one module per week.

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3 If a mentor/mentee dyad has not had a call within 2 weeks but has not indicated to the RA that  
4 they have terminated the programme, the RA will contact the participant to determine interest  
5 in continuing versus terminating their involvement or if they prefer to continue with just TTC  
6 programme. If they have decided to end the programme, they will be asked to fill out outcome  
7 measures. If scheduled calls are missed, participants will receive reminders by the mentor  
8 and/or the RA via email, text, or phone. We will control for the number of Skype calls made in  
9 the analyses.

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15 Characteristics of adherent versus non-adherent participants will be examined for systematic  
16 differences; when found, analyses will be conducted to determine effect on outcomes.

### 17 ***Losses to Follow-up***

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20 Every effort will be made to retain participants and to obtain post-treatment measures on all  
21 who enrolled. We will ask for multiple phone numbers (home, mobile phone) and/or email  
22 addresses. To minimize losses to follow-up, the RA may make calls, texts and emails reminding  
23 participants of timing of various online assessments.

### 24 25 26 27 28 29 **Data Analysis**

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31 All semi-structured interviews will be audio-taped and transcribed verbatim to determine  
32 satisfaction with the Irish TTC or TTC + iP2P programme.<sup>6</sup> The transcribed data will be  
33 managed using NVivo 11 computer software programme, which allows for online coding and  
34 annotation of text. We will use content analyses as outlined by Elo and Kygnäs, (2008).<sup>28</sup>

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Quantitative data will be analysed using SPSS version 21. Descriptive statistics will be used to describe sample characteristics at baseline. Rates of accrual drop out, compliance, and missing data with 95% confidence intervals will be calculated. For continuous outcomes, the normality of the data will be assessed using histograms and normal probability plots. If assumptions are met, continuous outcomes will be analysed using linear mixed modelling to assess effect over time. If the data is not normally distributed, non-parametric equivalents will be used. For binary outcomes, a logistic regression analysis will be conducted.

To inform sample size calculations and data analysis for a larger trial, data will be analysed as in a larger study, and estimates of variance and correlation (i.e., intra-cluster correlation within site) on physical (pain, fatigue) and emotional (anxiety, depression) symptoms, perceived social support, self- efficacy, adherence, knowledge, and HRQL will all be estimated. Analysis 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 outcomes using an analysis of covariance approach with post-treatment measures compared between groups using baseline

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3 scores as covariates. To control for type 1 error rate, Holm's Sequential correction will be  
4 applied. We will use the CONSORT<sup>29</sup> reporting guidelines to report this trial.

5  
6 Cost effectiveness and cost utility analyses will be conducted using both a healthcare system  
7 and societal perspective. Cost effectiveness and cost utility will be expressed as incremental  
8 cost effectiveness ratios (ICERs),<sup>30</sup> calculated by dividing the incremental costs between  
9 treatment arms by the incremental change in utility scores, measured as HRQL using the  
10 PedsQL. Multiple ICERs will be calculated comparing each of the three study groups in a  
11 pairwise fashion for both the cost effectiveness and cost utility analyses. Extensive  
12 deterministic and probabilistic sensitivity analysis will be performed to evaluate the robustness  
13 of the results. A 95% confidence interval for incremental costs, incremental effects, and the  
14 ICER will be calculated from study data using bootstrapping.

### 23 24 **Data monitoring and management**

25 This study will collect non-identifying, minimally invasive information, which is not expected  
26 to cause any level of distress to participants. All data will be collected electronically and stored  
27 securely at the Centre for Pain Research on password-protected databases that can only be  
28 accessed by the research team.

29 Should any participant - parent, adolescent or young adult - indicate at any point during the  
30 study that they no longer wish to participate, that decision will be respected. If they would like  
31 to have their data up to that point destroyed or not used in the final analyses, they can inform  
32 the researcher of their wishes and their data will be confidentially shredded.

### 39 40 41 **Ethical considerations:**

42 If an adolescent is found to be at risk of becoming distressed or not taking their meds,  
43 appropriate methods will be taken to inform those in positions of authority. The guidelines of  
44 the Child Protection Policy outlined by the respective hospital where the adolescent is being  
45 treated will be followed to ensure that they are fully supported throughout the project in relation  
46 to any issues that may arise. If an adolescent is considered to be at risk during the course of the  
47 project, a Senior Clinical Psychologist will be contacted by the researchers to provide  
48 appropriate guidance and consultation if necessary.

49 In accordance with the Ethical Guidance for research with children, all members of the research  
50 team will be Garda vetted and employment checks will be carried out.



All members of the research team will be trained and have access to relevant expertise in relation to child protection issues. All those researchers having face-to-face contact with the adolescents will have taken part in HSE Child First training.

Written consent and assent will be obtained from all participating adolescents, their parents and the young adult mentors. During the consent process, the study procedures will be described in detail to both parents and adolescents, giving time to read the information and opportunities to ask questions. All participants will be advised that they are able to stop their participation at any time.

### **Dissemination**

We will use both integrative and end-of-project knowledge exchange approaches to disseminate the findings to the public, patients with JIA and their families, support organisations, researchers and clinicians.

*Approach 1 will include:*

- (a) Involving key stakeholders in all stages of the research process from the outset. Key stakeholders include adolescents with JIA (represented by the YPAP, patient organisations and clinicians).
- (b) Presentation of research findings by the PI and co-applicants at National, European and International conferences, plus published in leading paediatric or rheumatology journals to target all practicing health care professionals.
- (c) Other strategies will include a 1-page report and YouTube video that will be:

1. Distributed to rheumatology health care professionals and patient groups across Ireland,
2. Included in media releases and posting/links on key websites (e.g., <http://www.juvenilearthritis.ie>) and social media,
3. Sent to all participants at the end of the project to inform them of the findings,
4. Included in conference presentations, which will be co-presented by researchers and stakeholders (e.g., adolescents with JIA, Arthritis Ireland or iCAN representative) where possible.

*Approach 2 will involve:* launching an interactive Internet conduit (“Irish Teens Taking Charge: Managing Arthritis Online” and peer mentoring) at the end of the project, if found to be effective, to share knowledge with users, predominately adolescents with JIA and their families, as well as other web audiences (e.g., peers, teachers, and health professionals).

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3 This mode of communication can provide an effective tool to help in the collection, processing  
4 and targeted distribution of information about JIA research to benefit patients and their  
5 families, clinicians, researchers, administrators, health care policy makers, school  
6 administrations and the public.  
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### 10 11 12 13 **Acknowledgements:**

14 All our collaborators and funders.

15 iCAN, Arthritis Ireland, all the families and HCP who are working with us on this project  
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### 20 21 **Funding Statement:**

22 This work is supported by Irish Health Research Board (HRB) and National  
23 Children's Hospital (NCHF), grant number - NCHF-2017-003.  
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### 28 29 **Conflict of interest:**

30 There are no conflicts of interest  
31

### 32 **Data are available upon reasonable request**

33 The on-line survey results and data from the qualitative elements of the study, once de-  
34 identified, will be available from Centre for Pain Research (CPR), School of Psychology,  
35 NUI Galway. The conditions for reuse will be decided by the CPR and SICK Kids Hospital  
36 team upon completion of analysis.  
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### 42 **Authors Statement:**

43  
44 Dr. Siobhan O'Higgins

- 45 • Successfully applied for the ethics in both university and hospital, recruited and  
46 trained both YPAPA and Mentors, co-created recruitment posters, parents invite  
47 letter, consent and assent forms. Liaised with HCP and families. Devised the lay out  
48 of the measures and the survey for all participants. Tested same and made  
49 amendments.  
50
- 51 • Wrote the paper and the protocol. Revised it critically for important intellectual  
52 content  
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- 54 • Approved final version  
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- 56 • Agrees to be accountable for all aspects of the work.  
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4 Professor Jennifer Stinson

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- 6 • Designed and rolled out Canadian TTC and iPeer2Peer. Oversaw all adaptations to the
  - 7 text and videos. Liaised with all HCP and families.
  - 8
  - 9 • Helped draft the paper and protocol and revised it critically for important intellectual
  - 10 content
  - 11
  - 12 • Gave final approval of the version published
  - 13
  - 14 • Agrees to be accountable for all aspects of the work

15 Dr. Sarah Aloha Kohut

- 16
- 17 • Designed and rolled out Canadian iP2P and oversaw adaptations to the training and
  - 18 planning of the mentoring aspect of the study. Helped design measures for the whole
  - 19 study to ensure questionnaire not too onerous for participants
  - 20
  - 21 • Revised the paper critically for important intellectual content.
  - 22
  - 23 • Gave final approval of the version published
  - 24
  - 25 • Agrees to be accountable for all aspects of the work.

26 Dr. Line Caes

- 27
- 28 • Involved with the design of the work, helped revise and then deliver the adapted
  - 29 training for the mentors.
  - 30
  - 31 • Supported the drafting of the paper and revised it critically for important intellectual
  - 32 content
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  - 34 • Gave final approval of the version published
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  - 36 • Agrees to be accountable for all aspects of the work.

37 Dr. Caroline Heary

- 38
- 39 • Involved in the design of the pilot RCT and selection of appropriate measures.
  - 40
  - 41 • Revised the paper critically for important intellectual content.
  - 42
  - 43 • Gave final approval of the version published
  - 44
  - 45 • Agrees to be accountable for all aspects of the work.

46 Professor Brian McGuire

- 47
- 48 • Co-designed the whole study, oversaw all engagement with participants and
  - 49 stakeholders, advised on selection of appropriate measures. Has final say on all
  - 50 aspects of the study as P.I.
  - 51
  - 52 • Revised the paper critically for important intellectual content.
  - 53
  - 54 • Gave final approval of the version published
  - 55
  - 56 • Agrees to be accountable for all aspects of the work.

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58 **Trial Registration:** Registration number: ISRCTN13535901.  
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5 **Figure Legends:**

6 Figure 1: Development of pilot RCT and future for full RCT of Irish Teens Taking Charge  
7 and iPeer2Peer  
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10 Figure 2: Schema of pilot RCT of TTC with iPeer2Peer

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12 Figure 3: Flowchart of pilot RCT  
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## References

1. Arthritis Ireland (2017). Retrieved from: <http://www.juvenilearthritis.ie>
2. Sawyer, M. G., Whitham, J. N., Robertson, D. M., Taplin, J. E., Varni, J. W., & Baghurst, P. A. (2004). The relationship between health-related quality of life, pain and coping strategies in juvenile idiopathic arthritis. *Rheumatology*, *43*(3), 325-330.
3. Stinson, J., Kohut, S. A., Forgeron, P., Amaria, K., Bell, M., Kaufman, M. & Spiegel, L. (2016). The iPeer2Peer program: a pilot randomized controlled trial in adolescents with juvenile idiopathic arthritis. *Pediatric Rheumatology*, *14*(1), 48.
4. Simons, L.E., Logan, D.E., Chastain, L. & Cerullo, M. (2010). Engagement in Multidisciplinary interventions for pediatric chronic pain: parental expectations, barriers, and child outcomes. *Clinical Journal of Pain*, *26*, 291–299.
5. Stinson, J., McGrath, P., Hodnett, E., Feldman, B., Duffy, C., Huber, A. & Campillo, S. (2010). Usability testing of an online self-management program for adolescents with juvenile idiopathic arthritis. *Journal of Medical Internet Research*, *12*(3), e30.
6. Stinson, J. N., McGrath, P. J., Hodnett, E. D., Feldman, B. M., Duffy, C. M., Huber, A. M. & Campillo, S. (2010). An internet-based self-management program with telephone support for adolescents with arthritis: a pilot randomized controlled trial. *The Journal of Rheumatology*, *37*(9), 1944-1952.
7. Dennis, C.L. (2003). Peer support within a health care context: A concept analysis. *International Journal of Nursing Studies*, *40*(3), 321–332.
8. Kohut, S. & Stinson, J. (2014). Systematic review of peer support interventions for adolescents with chronic illness: A narrative analysis. *International Journal of Child and Adolescent Health*, *7*, 183-197.
9. Sandhu, S., Veinot, P., Embuldeniya, G., Brooks, S., Sale, J., Huang, S. & Bell, M. J. (2013). Peer-to-peer mentoring for individuals with early inflammatory arthritis: feasibility pilot. *BMJ open*, *3*(3), e002267.
10. Zelikovsky, N. & Petrongolo, J. (2013). Utilizing peer mentors for adolescents with chronic health conditions: Potential benefits and complications. *Pediatric transplantation*, *17*(7), 589-591.
11. Kohut, S. A., Stinson, J. N., Ruskin, D., Forgeron, P., Harris, L., van Wyk, M. & Campbell, F. (2016). iPeer2Peer program: a pilot feasibility study in adolescents with chronic pain. *Pain*, *157*(5), 1146-1155.
12. Ford P. (2017). The app route to patient engagement. *HIMSS Europe*, *5*(3),

1  
2  
3 16-17  
4

- 5 13. O'Sullivan, G., O'Higgins, S., Caes L., Saetes, S., McGuire, B.E., & Stinson, J., (accepted  
6 October 2018). Self-management needs of Irish adolescents with Juvenile Idiopathic Arthritis  
7 (JIA): how can a Canadian web-based programme meet these needs? *Journal of Pediatric*  
8 *Rheumatology*.  
9  
10  
11  
12 14. Stinson, J & O'Higgins S., (2019) Pushing the frontier of Digital Health to  
13 transform Paediatric self- management (Power point presentation to Health  
14 Care Providers in Temple Street Children's Hospital, Dublin).  
15  
16 15. Hertzog, M.A. (2008). Considerations in determining sample size for pilot  
17 studies. *Research in Nursing & Health*, 31, 180–191.  
18  
19 16. Arain, M., Campbell, M. J., Cooper, C. L. & Lancaster, G. A. (2010). What is a pilot  
20 or feasibility study? A review of current practice and editorial policy. *BMC medical*  
21 *research methodology*, 10(1), 67.  
22  
23 17. André M, Hedengren E, Hagelberg S, Stenström CH. Perceived ability to manage  
24 juvenile chronic arthritis among adolescents and parents: development of a  
25 questionnaire to assess medical issues, exercise, pain, and social support. *Arthritis Care*  
26 *Res.* 1999;12(4):229-237.  
27  
28 18. Klassen AF, Grant C, Barr R, et al. Development and validation of a generic scale for  
29 use in transition programmes to measure self-management skills in adolescents with  
30 chronic health conditions: the TRANSITION-Q. *Child Care Health Dev.*  
31 2014;41(4):547-558.  
32  
33 19. Varni, W. J., Seid, M., Smith Knight, T., Burwinkle, T., Brown, J., Szer, I., The  
34 PedsQL™ in pediatric rheumatology: Reliability, validity, and responsiveness of the  
35 Pediatric Quality of Life Inventory™ Generic Core Scales and Rheumatology Module.  
36 *Arthritis & Rheumatology* 2002: 46(3):714-25.  
37  
38 20. Jacobson, C.J., Kashikar-Zuck, S., Farrell, J., Barnett, K., Goldschneider, K., Dampier,  
39 C., Cunningham, N., Crosby, L. & DeWitt, E.M. (2015). Qualitative evaluation of  
40 pediatric pain, behavior, quality and intensity item candidates and the PROMIS pain  
41 domain framework in children with chronic pain. *J Pain.* 16(12), 1243-55.  
42  
43 21. Chorpita, B. F., Yim, L., Moffitt, C., Umemoto, L. A., Francis, S. E., Assessment of  
44 symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and  
45 depression scale. *Behaviour Research and Therapy.* 2000; 38(8), 835-855.  
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57  
58  
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60
22. Chorpita, B. F., Ebesutani, C., Spence, S., Revised Children's Anxiety and Depression Scale, User Guide. 2015 downloaded from [www.childfirst.ucla.edu](http://www.childfirst.ucla.edu) 22.04.2018.
  23. Brady Teresa J. (2011) Measures of self-efficacy: Arthritis Self-Efficacy Scale (ASES), Arthritis Self-Efficacy Scale-8 Item (ASES-8), Children's Arthritis Self-Efficacy Scale (CASE), Chronic Disease Self-Efficacy Scale (CDSSES), Parent's Arthritis Self-Efficacy Scale (PASE), and Rheumatoid Arthritis Self-Efficacy Scale (RASE). *Arthritis Care & Research*. 2011; 63 (S11): S473-
  24. DeWalt DA, Thissen D, Stucky BD, Langer MM. PROMIS pediatric peer relationships scale: Development of a peer relationships item bank as part of social health measurement. *Health Psychology*. 2013; 32(10):1093-1103.
  25. Moretti ME A cost-effectiveness analysis of maternal genotyping to guide treatment for postpartum pain and avert infant adverse events. [PhD Dissertation] Toronto, Canada: Institute of Health Policy Management and Evaluation, University of Toronto; 2014.
  26. De Civita, M., Dobkin, P., Ehrmann-Feldman, D., Karp, I., Duffy, C. Development and Preliminary Reproducibility and Validity of the Parent Adherence Report Questionnaire: A Measure of Adherence in Juvenile Idiopathic Arthritis. *Journal of Clinical Psychology in Medical Settings*. 2005; 12(1): 1-12.
  27. Brodeur P, Larose S, Tarabulsky G, Feng B, Forget-Dubois N. Development and Construct Validation of the Mentor Behavior Scale. *Mentoring & Tutoring: Partnership in Learning*. 2015;23(1):54-75.
  28. Elo, S. & Kyngäs, H. (2008). The qualitative content analysis process. *Journal of Advanced Nursing*, 62(1), 107-115.
  29. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.
  30. Bensink, M., Wootton, R., Irving, H., Hallahan, A., Theodoros, D., Russell, T. & Barnett, A. G. (2007). Investigating the cost-effectiveness of video telephone based support for newly diagnosed paediatric oncology patients and their families: design of a randomised controlled trial. *BMC health services research*, 7(1), 38.



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## Steps in Development, Evaluation and Future plans



### PHASE 1

- Needs assessment + what changes needed to make TTC relatable to Irish context (HCP, teens and parents)



### PHASE 2

- Irish TTC usability tested (HCP, teens and parents)
- Mentors trained and ready for SKYPE mentoring



### PHASE 3

- Feasibility and preliminary outcome testing (pilot RCT) with 3 arms - Control, TTC, TTC+iP2P



### PHASE 4 – in the future

- Multi-centred RCT

Figure 1: Development of pilot RCT and future for full RCT of Irish Teens Taking Charge and iPeer2Peer

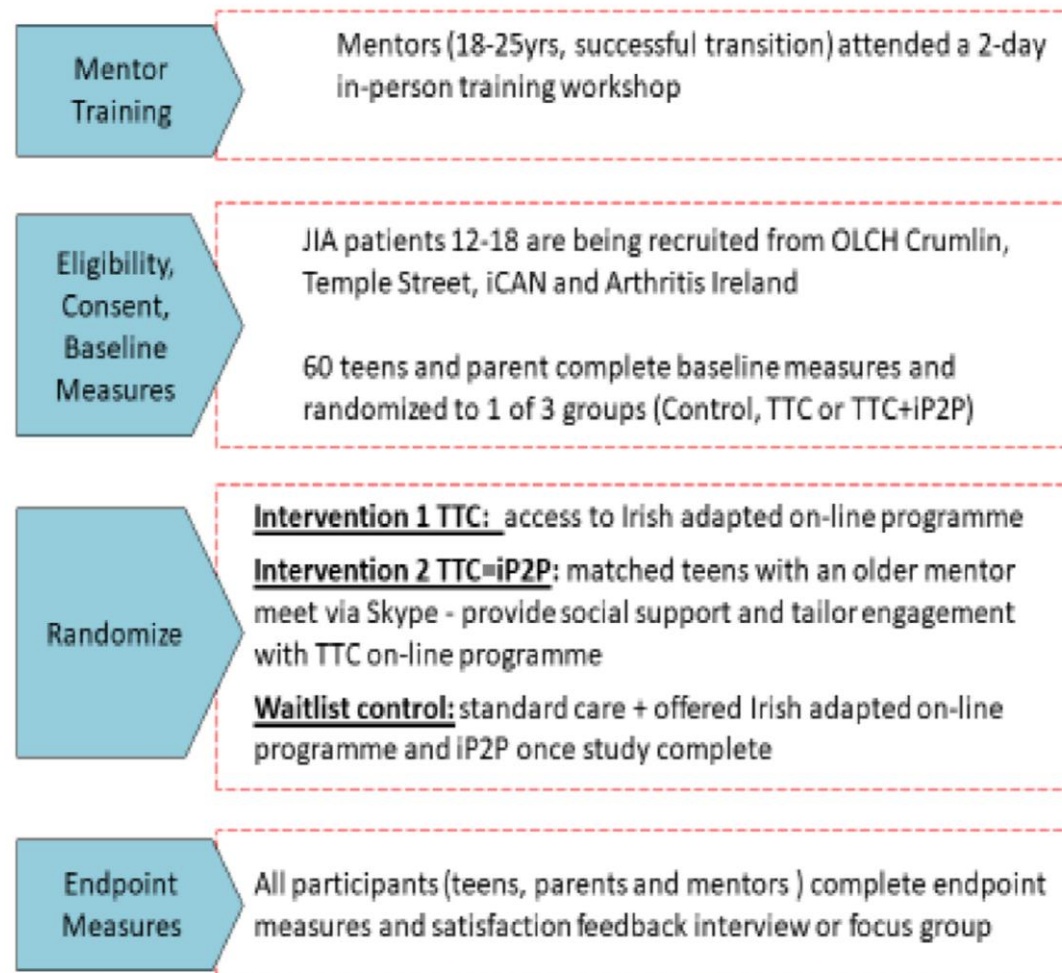
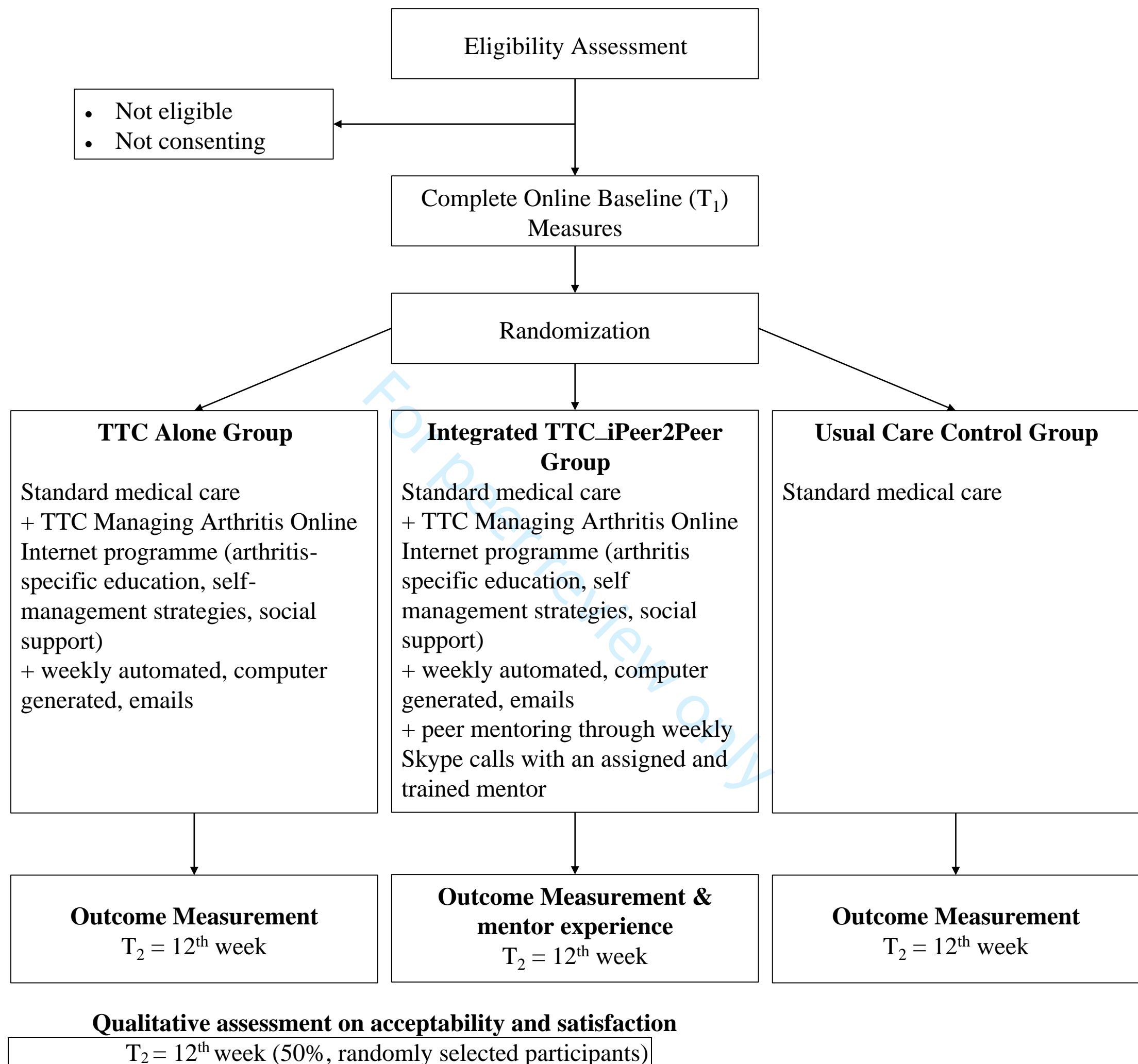


Figure 2: Schema of pilot RCT of TTC with iPeer2Peer



**Figure 3: Flowchart of pilot RCT**



## CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-5
	2b	Specific objectives or research questions for pilot trial	5
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	9-12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	
Sample size	7a	Rationale for numbers in the pilot trial	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7

1	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
2	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
3		11b	If relevant, description of the similarity of interventions	7-8
4	Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9-12
5	<b>Results</b>			
6	Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	n/a
7		13b	For each group, losses and exclusions after randomisation, together with reasons	n/a
8	Recruitment	14a	Dates defining the periods of recruitment and follow-up	n/a
9		14b	Why the pilot trial ended or was stopped	n/a
10	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	n/a
11	Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	n/a
12	Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	n/a
13	Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
14	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
15		19a	If relevant, other important unintended consequences	
16	<b>Discussion</b>			
17	Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	n/a
18	Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	n/a
19	Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	n/a
20		22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	n/a
21	<b>Other information</b>			
22	Registration	23	Registration number for pilot trial and name of trial registry	3,17
23	Protocol	24	Where the pilot trial protocol can be accessed, if available	
24	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15
25		26	Ethical approval or approval by research review committee, confirmed with reference number	1

1 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.  
2 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important  
3 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological  
4 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).  
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# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

			Page
		Reporting Item	Number
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	2,17

1	Trial registration:	<a href="#">#2b</a>	All items from the World Health Organization Trial	n/a
2				
3	data set		Registration Data Set	
4				
5				
6	Protocol version	<a href="#">#3</a>	Date and version identifier	
7				
8				
9	Funding	<a href="#">#4</a>	Sources and types of financial, material, and other	16
10			support	
11				
12				
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14				
15	Roles and	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	1,16,17
16				
17	responsibilities:			
18				
19	contributorship			
20				
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22				
23	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	2,17
24				
25	responsibilities:			
26				
27	sponsor contact			
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29	information			
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32	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	n/a
33				
34	responsibilities:		design; collection, management, analysis, and	
35				
36	sponsor and funder		interpretation of data; writing of the report; and the	
37				
38			decision to submit the report for publication, including	
39				
40			whether they will have ultimate authority over any of	
41				
42			these activities	
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47	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the	n/a
48				
49	responsibilities:		coordinating centre, steering committee, endpoint	
50				
51	committees		adjudication committee, data management team, and	
52				
53			other individuals or groups overseeing the trial, if	
54				
55			applicable (see Item 21a for data monitoring committee)	
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1	Background and	<a href="#">#6a</a>	Description of research question and justification for	3-6
2				
3	rationale		undertaking the trial, including summary of relevant	
4				
5			studies (published and unpublished) examining benefits	
6				
7			and harms for each intervention	
8				
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10				
11	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	6-7
12				
13	rationale: choice of			
14				
15	comparators			
16				
17				
18	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	6
19				
20				
21				
22	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg,	7
23				
24			parallel group, crossover, factorial, single group),	
25				
26			allocation ratio, and framework (eg, superiority,	
27				
28			equivalence, non-inferiority, exploratory)	
29				
30				
31				
32	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	7
33				
34			academic hospital) and list of countries where data will	
35				
36			be collected. Reference to where list of study sites can	
37				
38			be obtained	
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42	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If	7
43				
44			applicable, eligibility criteria for study centres and	
45				
46			individuals who will perform the interventions (eg,	
47				
48			surgeons, psychotherapists)	
49				
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51	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow	8-9
52				
53	description		replication, including how and when they will be	
54				
55			administered	
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1	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated	n/a
2				
3	modifications		interventions for a given trial participant (eg, drug dose	
4			change in response to harms, participant request, or	
5			improving / worsening disease)	
6				
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11	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention	6,12,13
12				
13	adherence		protocols, and any procedures for monitoring adherence	
14			(eg, drug tablet return; laboratory tests)	
15				
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19	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are	n/a
20			permitted or prohibited during the trial	
21	concomitant care			
22				
23				
24	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the	9-12
25			specific measurement variable (eg, systolic blood	
26			pressure), analysis metric (eg, change from baseline,	
27			final value, time to event), method of aggregation (eg,	
28			median, proportion), and time point for each outcome.	
29			Explanation of the clinical relevance of chosen efficacy	
30			and harm outcomes is strongly recommended	
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41	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any	7
42			run-ins and washouts), assessments, and visits for	
43			participants. A schematic diagram is highly	
44			recommended (see Figure)	
45				
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51	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve	9
52			study objectives and how it was determined, including	
53			clinical and statistical assumptions supporting any	
54			sample size calculations	
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1	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment	3,5,6,7
2			to reach target sample size	
3				
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5				
6	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence (eg,	8
7	generation		computer-generated random numbers), and list of any	
8			factors for stratification. To reduce predictability of a	
9			random sequence, details of any planned restriction (eg,	
10			blocking) should be provided in a separate document that	
11			is unavailable to those who enrol participants or assign	
12			interventions	
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23	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg,	8
24	concealment		central telephone; sequentially numbered, opaque,	
25			sealed envelopes), describing any steps to conceal the	
26	mechanism		sequence until interventions are assigned	
27				
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33	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol	8
34	implementation		participants, and who will assign participants to	
35			interventions	
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41	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg,	8
42			trial participants, care providers, outcome assessors,	
43			data analysts), and how	
44				
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47				
48	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is	8
49	emergency		permissible, and procedure for revealing a participant's	
50			allocated intervention during the trial	
51	unblinding			
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1	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome,	9-12
2			baseline, and other trial data, including any related	
3			processes to promote data quality (eg, duplicate	
4			measurements, training of assessors) and a description	
5			of study instruments (eg, questionnaires, laboratory	
6			tests) along with their reliability and validity, if known.	
7				
8			Reference to where data collection forms can be found, if	
9			not in the protocol	
10				
11	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and complete	12-13
12	retention		follow-up, including list of any outcome data to be	
13			collected for participants who discontinue or deviate from	
14			intervention protocols	
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20	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage,	14
21			including any related processes to promote data quality	
22			(eg, double data entry; range checks for data values).	
23			Reference to where details of data management	
24			procedures can be found, if not in the protocol	
25				
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30	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary	13-14
31			outcomes. Reference to where other details of the	
32			statistical analysis plan can be found, if not in the	
33			protocol	
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42	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and	n/a
43	analyses		adjusted analyses)	
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1	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-	13
2				
3	population and		adherence (eg, as randomised analysis), and any	
4				
5	missing data		statistical methods to handle missing data (eg, multiple	
6				
7			imputation)	
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11	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC);	n/a
12				
13	formal committee		summary of its role and reporting structure; statement of	
14				
15			whether it is independent from the sponsor and	
16			competing interests; and reference to where further	
17			details about its charter can be found, if not in the	
18			protocol. Alternatively, an explanation of why a DMC is	
19			not needed	
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28	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping	n/a
29				
30	interim analysis		guidelines, including who will have access to these	
31				
32			interim results and make the final decision to terminate	
33				
34			the trial	
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38	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing	n/a
39				
40			solicited and spontaneously reported adverse events and	
41				
42			other unintended effects of trial interventions or trial	
43				
44			conduct	
45				
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47				
48	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if	n/a
49				
50			any, and whether the process will be independent from	
51				
52			investigators and the sponsor	
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54				
55	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee /	1
56				
57	approval		institutional review board (REC / IRB) approval	
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1 2 3 4 5 6 7 8 9 10	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
11 12 13 14 15 16 17 18	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
19 20 21 22 23 24 25	Consent or assent: ancillary studies	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
26 27 28 29 30 31 32 33 34 35	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	6,14
36 37 38 39 40 41	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall trial and each study site	16
42 43 44 45 46 47 48	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
49 50 51 52 53 54 55 56 57 58 59 60	Ancillary and post trial care	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a

1	Dissemination	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial	15-16
2				
3	policy: trial results		results to participants, healthcare professionals, the	
4			public, and other relevant groups (eg, via publication,	
5			reporting in results databases, or other data sharing	
6			arrangements), including any publication restrictions	
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13	Dissemination	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of	n/a
14				
15	policy: authorship		professional writers	
16				
17				
18				
19	Dissemination	<a href="#">#31c</a>	Plans, if any, for granting public access to the full	n/a
20				
21	policy: reproducible		protocol, participant-level dataset, and statistical code	
22				
23	research			
24				
25				
26	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation	Appendix
27				
28	materials		given to participants and authorised surrogates	
29				
30				
31				
32	Biological	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of	n/a
33				
34	specimens		biological specimens for genetic or molecular analysis in	
35			the current trial and for future use in ancillary studies, if	
36			applicable	
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43 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made  
44 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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