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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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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 up-dated 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,[1] 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). [2, 3] 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. [2, 3] 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),[4] 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

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

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.[12] 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.[13]

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).

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).

Objective:

To explore feasibility and preliminary effectiveness of iP2P mentoring programme along with an Irish version of "Teens Taking Charge: Managing Arthritis Online" to help adolescents with JIA improve their self-management skills, HRQL, disease knowledge, social support, self-efficacy, physical symptoms and emotional distress, compared to a treatment as usual control group.

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.
2. The involvement of the Young People Advisory Panel as well as Arthritis Ireland (AI) and iCAN (collaborators on the Lending an Ear project) 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 to explore whether interventions such as TTC and iP2P would be welcomed and useful to them.[13]

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 we will be using on-line pre and post the intervention.

The YPAP met initially – courtesy of their parents bringing them to a central location - for a day's training as a research support panel and now meet either via WhatsApp or schedules ZOOM meetings.

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

Hence, from the start of this process, stakeholder have reviewed serval times the on-line intervention, and given us 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

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

Participant Eligibility

Inclusion criteria:

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

Exclusion criteria

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

Recruitment

Three recruitment avenues to secure sufficient participants:

i) OLCH Crumlin: All registered and eligible patients of the Paediatric Rheumatology programme will be sent an invitation to participate. This method will be supplemented by purposive sampling of patients attending regularly scheduled clinic visits, to achieve desired number of participants.

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

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

Randomisation

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

Description of study arms

(a) The control group will receive their usual healthcare appointments, medication and therapies.

(b) Experimental groups

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

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

The TTC programme will be delivered on restricted password-protected website that allows the team to track usage. The TTC programme is set up in a modular fashion; 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 adolescents with JIA within the experimental group in the pilot RCT of the original TTC.[6] 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 prior to the programme. 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). [11] However, we will advise weekly contact. The aim will be for a maximum of 12 calls within a 15-week period.

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.[14,15] 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)[16] 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) [17] 3 point scale, 14 items.
- HRQL (PedsQL Arthritis Module)[18] 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)[19] 5 point scale, (8 items).
- Revised Children's Anxiety and Depression Scale (RCADS) [20, 21] - 25 items, with subscale scores for depression and anxiety as well as an overall internalising score.

- Disease knowledge (MEPS)[16] 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) [22] 5 point scale, (11 items)
- Perceived social support (PROMIS Paediatric Profile Peer Relationship Scale).[23] Short form 5 point scale, (8 items)
- Health Services Use and Out-of-Pocket Expense Diary-Youth Version[24] 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). [18]
- Adherence (Adherence report questionnaire; PARQ) [25] 1-7 measures, scale of 10
- Medical issues (Medical Issues Questionnaire)[16] (9 items).
- Self-efficacy (Parent Arthritis Self-Efficacy; PASE) [22] 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.[19] 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 [11]
- 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) [26]

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

and/or the RA via email, text, or phone. We will control for the number of Skype calls made in the analyses.

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

Losses to Follow-up

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

Data Analysis

All semi-structured interviews will be audio-taped and transcribed verbatim to determine satisfaction with the Irish TTC or TTC + iP2P programme.[6] The transcribed data will be managed using NVivo 11 computer software programme, which allows for online coding and annotation of text. We will use content analyses as outlined by Elo and Kygnäs, (2008).[27]

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. The normality of the data will be assessed using histograms and normal probability plots and if assumptions are met, then a parametric statistics approach will be taken to analysis.

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 scores as covariates. To control for type 1 error rate, Holm's Sequential correction will be applied. We will use the SPIRIT [28] reporting guidelines to report this trial.

Cost effectiveness and cost utility analyses will be conducted using both a healthcare system and societal perspective. Cost effectiveness and cost utility will be expressed as incremental cost effectiveness ratios (ICERs),[29] calculated by dividing the incremental costs between treatment arms by the incremental change in utility scores, measured as HRQL using the PedsQL. Multiple ICERS will be calculated comparing each of the three study groups in a

pairwise fashion for both the cost effectiveness and cost utility analyses. Extensive deterministic and probabilistic sensitivity analysis will be performed to evaluate the robustness of the results. A 95% confidence interval for incremental costs, incremental effects, and the ICER will be calculated from study data using bootstrapping.

Data monitoring and management

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

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

If an adolescent is found to be at risk, appropriate methods will be taken to inform those in positions of authority. The guidelines of the Child Protection Policy outlined by the respective hospital where the adolescent is being treated will be followed to ensure that they are fully supported throughout the project in relation to any issues that may arise. If an adolescent is considered to be at risk during the course of the project, a Senior Clinical Psychologist will be contacted by the researchers to provide appropriate guidance and consultation if necessary.

In accordance with the Ethical Guidance for research with children, all members of the research 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.

Additionally, 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 each individual time to read the information and the opportunity to ask questions. Adolescents and parents will also 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 (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. [30]

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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.

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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.

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

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	14
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6-10
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5-6

Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-7
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	7,11
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	5
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that	6

		is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	6
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	6
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-11
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11-13
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the	11-12

		statistical analysis plan can be found, if not in the protocol	
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	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
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13

Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	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	12
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	13-14
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

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

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

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Keywords:
Juvenile Rheumatoid Arthritis, Adolescent Stakeholder involvement, Quality of life, Self-care, Online interventions

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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.

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,[1] 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). [2, 3] 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. [2, 3] 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 in Canada. So, although cognitive-behavioural therapy (CBT) interventions can lead to improvement in pain and HRQL,[4] most young people with JIA in Ireland will not receive these interventions as teens 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 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 coach (trained, adult non-Health Care Professionals (HCP) without arthritis) for Canadian adolescents with JIA.[3,5,6] Significant improvements were found in disease-related knowledge, decreased pain and increased exercise adherence.[6] Peer support by another person with similar chronic illness is associated with improved health outcomes.[7-10] iPeer2Peer (iP2P), an online peer mentoring programme, was evaluated with adolescents with chronic pain, and found to improve acceptability of self-management and peer support treatments. [11] Although positively evaluated separately working with teens with JIA the two programmes have not be combined before.

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.[12] 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.[13]

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[14].

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-

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

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

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 (collaborators on the Lending an Ear project) 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 to explore whether interventions such as TTC and iP2P would be welcomed and useful to them.[13]

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 we will be using 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 as a young research support panel. 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.

Hence, from the start of this process, stakeholders have reviewed several times the on-line intervention, and given us 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

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

Participant Eligibility

Inclusion criteria:

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

Exclusion criteria

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

Recruitment

Three recruitment avenues to secure sufficient participants:

i) OLCH Crumlin: All registered and eligible patients of the Paediatric Rheumatology programme will be sent an invitation to participate, by the HCP. This method will be

supplemented by inviting patients attending regularly scheduled clinic visits, to achieve desired number of participants, by the research team.

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

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

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

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

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

Randomisation

When a participant agrees to take part in the trial they will be randomly assigned to one of the three arms using random permuted blocks to ensure groups are balanced. Randomisation will be performed using 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. Participants will complete the initial on-line T1 measures and then once assigned to a group emailed with their specific details for involvement over the next 12 weeks.

Description of study arms

(a) The control group will receive their usual healthcare appointments, medication and therapies, which may include physiotherapy, occupational therapy and talking with a psychologist (these may be 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, adolescents with JIA in the two experimental groups will receive interactive multi-component self-guided online TTC intervention which consists of 12 modules for teens. There are also two modules specifically for parents/care-givers to help encourage healthy behaviour.

The TTC programme will be delivered on restricted password-protected website that allows the team to track usage. The TTC programme is set up in a modular fashion; 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 adolescents with JIA within the experimental group in the pilot RCT of the original TTC.[6] 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 prior to the programme. 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). [11] However, we will advise weekly contact. The aim will be for a maximum of 12 calls within a 15-week period.

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.[15,16] 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 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)[17] 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) [18] 3 point scale, 14 items.
- HRQL (PedsQL Arthritis Module)[19] 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)[20] 5-point scale, (8 items).
- Revised Children's Anxiety and Depression Scale (RCADS) [21, 22] - 25 items, with subscale scores for depression and anxiety as well as an overall internalising score.
- Disease knowledge (MEPS)[17] 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) [23] 5-point scale, (11 items)
- Perceived social support (PROMIS Paediatric Profile Peer Relationship Scale).[24] Short form 5 point scale, (8 items)
- Health Services Use and Out-of-Pocket Expense Diary-Youth Version[25] 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). [19]
- Adherence (Adherence report questionnaire; PARQ) [26] 1-7 measures, scale of 10
- Medical issues (Medical Issues Questionnaire)[17] (9 items).
- Self-efficacy (Parent Arthritis Self-Efficacy; PASE) [23] 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.[20] 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 [11]
- 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) [27]

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.

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 and/or the RA via email, text, or phone. We will control for the number of Skype calls made in the analyses.

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

Losses to Follow-up

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

Data Analysis

All semi-structured interviews will be audio-taped and transcribed verbatim to determine satisfaction with the Irish TTC or TTC + iP2P programme.[6] The transcribed data will be

managed using NVivo 11 computer software programme, which allows for online coding and annotation of text. We will use content analyses as outlined by Elo and Kygnäs, (2008).[28]

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 scores as covariates. To control for type 1 error rate, Holm's Sequential correction will be applied. We will use the CONSORT[29] reporting guidelines to report this trial.

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

Data monitoring and management

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

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

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

In accordance with the Ethical Guidance for research with children, all members of the research 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.

Additionally, 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 each individual time to read the information and the opportunity to ask questions. Adolescents and parents will also 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 (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.

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Conflict of interest:

There are no conflicts of interest

Authors Statement:

Dr. Siobhan O'Higgins

- Successfully applied for the ethics in both university and hospital, recruited and trained both YPAPA and Mentors, devised recruitment posters, parents invite letter,

consent and assent forms. Liaised with HCP and families. Devised the lay out of the measures and the survey for all participants. Tested same and made amendments.

- Wrote the paper and the protocol. Revised it critically for important intellectual content
- Approved final version
- Agrees to be accountable for all aspects of the work.

Professor Jennifer Stinson

- Designed and rolled out Canadian TTC andiPeer2Peer. Oversaw all adaptions to the text and videos. Liaised with all HCP and families.
- Helped to draft the paper and the protocol and revised it critically for important intellectual content
- Gave final approval of the version published
- Agrees to be accountable for all aspects of the work

Dr. Sarah Aloha Kohut

- Designed and rolled out Canadian iP2P and oversaw adaptions to the training and planning of the mentoring aspect of the study. Helped design the measures for the whole study to ensure questionnaire not too onerous for participants
- Revised the paper critically for important intellectual content.
- Gave final approval of the version published
- Agrees to be accountable for all aspects of the work.

Dr. Line Caes

- Involved with the design of the work, helped revise and then deliver the adapted training for the mentors.
- Supported the drafting of the paper and also revised it critically for important intellectual content
- Gave final approval of the version published
- Agrees to be accountable for all aspects of the work.

Dr. Caroline Heary

- Involved in the design of the pilot RCT and selection of appropriate measures.
- Revised the paper critically for important intellectual content.
- Gave final approval of the version published
- Agrees to be accountable for all aspects of the work.

Professor Brian McGuire

- Designed the whole study, oversaw all engagement with participants and stakeholders, advised on selection of appropriate measures. Has final say on all aspects of the study as P.I.
- Revised the paper critically for important intellectual content.
- Gave final approval of the version published
- Agrees to be accountable for all aspects of the work.

Trial Registration

Registration number: ISRCTN13535901.

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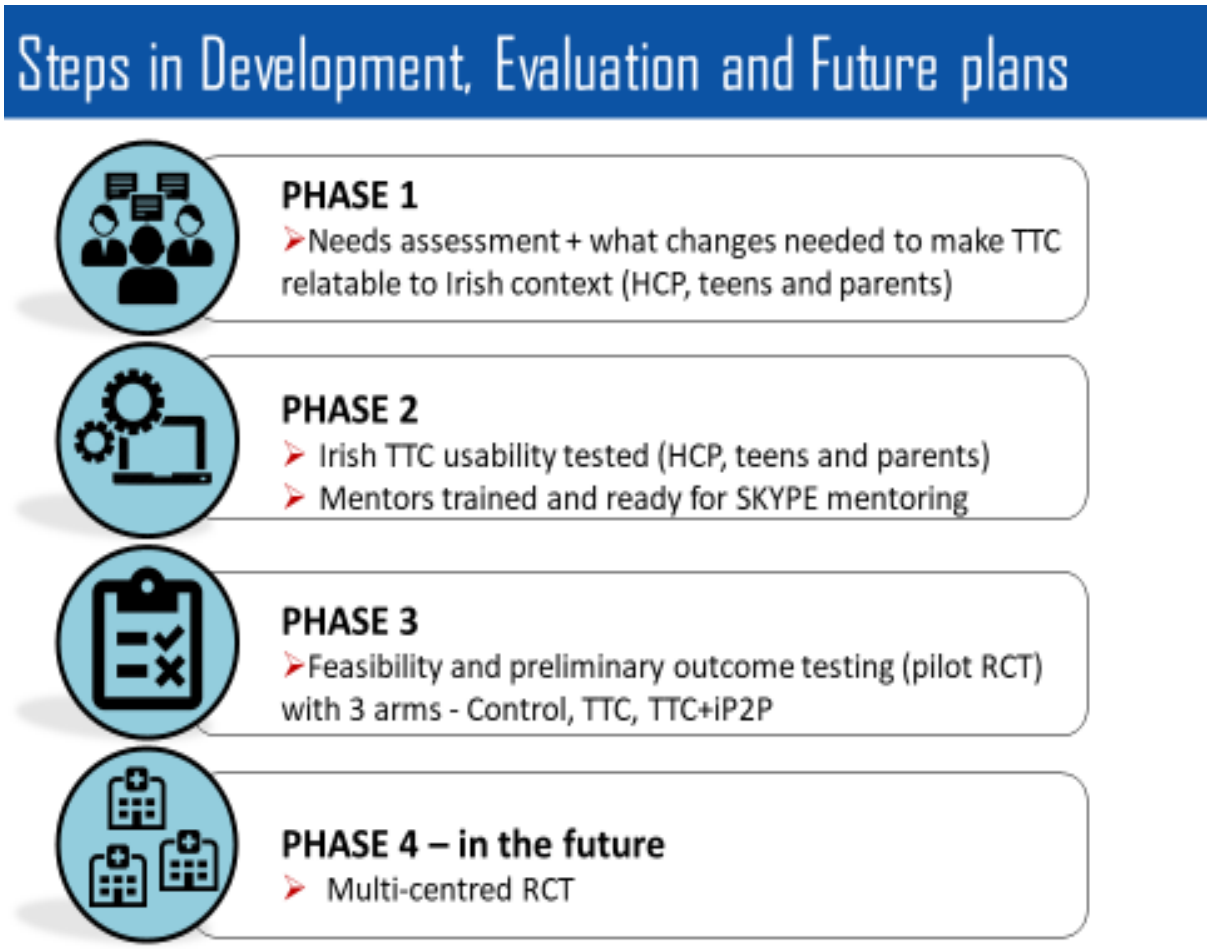
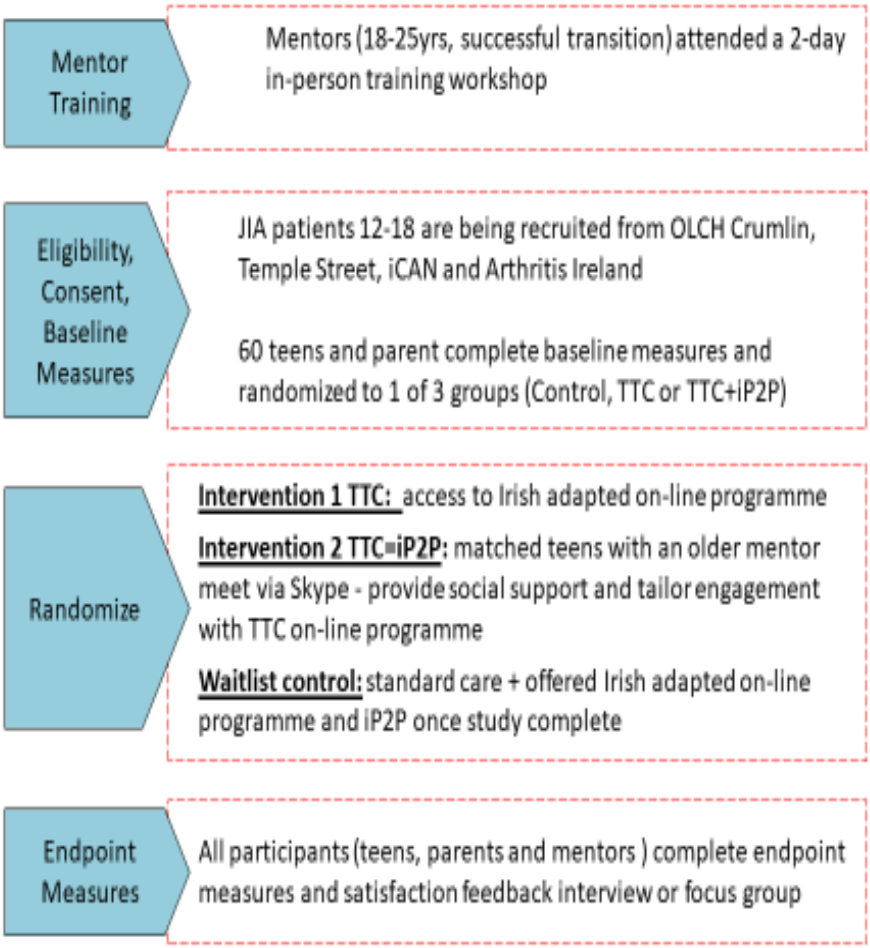
Development of pilot RCT and future for full RCT of Irish Teens Taking Charge and iPeer2Peer

Figure 1



Schema of pilot RCT of TTC with iPeer2Peer

Figure 2



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

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	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
Introduction			
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
Methods			
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

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

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological 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.

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:	*BMJ Open*
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
Primary Subject Heading:	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

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

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Keywords:
Juvenile Rheumatoid Arthritis, Adolescent Stakeholder involvement, Quality of life, Self-care, Online interventions

Word count: 4391

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.[1] 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). [2, 3] 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. [2, 3] 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,[4] 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

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

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.[12] 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.[13]

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.

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 lifestyle, skills to move on to adult health care, education and vocational skills to manage JIA);
3. Social support (videos, and stories of hope).

The Irish TTC has videos of Irish teens with JIA and their parents and HCP talking about the different topics, integrated with videos of Canadians, throughout the 12 modules. The text has been adapted with relevant drugs, service and financial support offered in Ireland rather than those in Canada. This process has taken a year to achieve and Sick Kids Hospital adapted the on-line TTC to incorporate 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 Figures 2 [14] and 3..

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-efficacy, physical symptoms and emotional distress, compared to a treatment as usual control group.
- Determine feasibility and sample size for a full RCT;
- Ensure active involvement of adolescents with JIA throughout the study with creation and support of a Young Person Advisory Panel (YPAP), who communicate monthly with the research team via ZOOM calls and WhatsApp group messaging. They and their parents reviewed the videos and text of the Irish TTC, posters and all recruitment information sent out to parents and teens.
- To examine how participants experienced the study
- To see if TTC and iP2P and TTC reduce costs for families of teens with JIA.

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.[13]

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

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

Participant Eligibility

Inclusion criteria:

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

Exclusion criteria

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

Recruitment

Three recruitment avenues:

i)All registered and eligible patients of OLCH Crumlin Paediatric Rheumatology programme will be sent an invitation to participate, by the HCP. Plus the research team will invite patients attending regularly scheduled clinic visits.

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

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

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

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

All potential participants will be contacted, consent and assent forms as well as detailed information emailed or sent to each family, to be returned signed prior to randomisation.

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 viaa 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 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.[6] 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). [11] However, we will advise weekly contact. The aim will be for a maximum of 12 calls within 15-weeks.

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.[15,16] 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 following a day's training in research methods and exploration of their role as a team of experts, 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 is vital to ensure that teens with JIA and their families retain 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 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.

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). 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.
- 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)[17] 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) [18] 3-point scale, 14 items.
- HRQL (PedsQL Arthritis Module)[19] 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)[20] 5-point scale, (8 items).
- Revised Children's Anxiety and Depression Scale (RCADS) [21, 22] - 25 items, with subscale scores for depression and anxiety as well as an overall internalising score.
- Disease knowledge (MEPS)[17] 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) [23] 5-point scale, (11 items)
- Perceived social support (PROMIS Paediatric Profile Peer Relationship Scale).[24] Short form 5-point scale, (8 items)
- Health Services Use and Out-of-Pocket Expense Diary-Youth Version[25] 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). [19]
- Adherence (Adherence report questionnaire; PARQ) [26] 1-7 measures, scale of 10
- Medical issues (Medical Issues Questionnaire)[17] (9 items).
- Self-efficacy (Parent Arthritis Self-Efficacy; PASE) [23] 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.[20] 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 [11]
- 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) [27]

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.

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 and/or the RA via email, text, or phone. We will control for the number of Skype calls made in the analyses.

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

Losses to Follow-up

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

Data Analysis

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

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

scores as covariates. To control for type 1 error rate, Holm's Sequential correction will be applied. We will use the CONSORT[29] reporting guidelines to report this trial.

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

Data monitoring and management

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

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

Ethical considerations:

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

In accordance with the Ethical Guidance for research with children, all members of the research 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).

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.

Acknowledgements:

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

Funding Statement:

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Conflict of interest:

There are no conflicts of interest

Data are available upon reasonable request

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

Authors Statement:

Dr. Siobhan O'Higgins

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

Professor Jennifer Stinson

- Designed and rolled out Canadian TTC andiPeer2Peer. Oversaw all adaptions to the text and videos. Liaised with all HCP and families.
- Helped draft the paper and protocol and revised it critically for important intellectual content
- Gave final approval of the version published
- Agrees to be accountable for all aspects of the work

Dr. Sarah Aloha Kohut

- Designed and rolled out Canadian iP2P and oversaw adaptions to the training and planning of the mentoring aspect of the study. Helped design measures for the whole study to ensure questionnaire not too onerous for participants
- Revised the paper critically for important intellectual content.
- Gave final approval of the version published
- Agrees to be accountable for all aspects of the work.

Dr. Line Caes

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

Dr. Caroline Heary

- Involved in the design of the pilot RCT and selection of appropriate measures.
- Revised the paper critically for important intellectual content.
- Gave final approval of the version published
- Agrees to be accountable for all aspects of the work.

Professor Brian McGuire

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

Trial Registration: Registration number: ISRCTN13535901.

Figure Legends:

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

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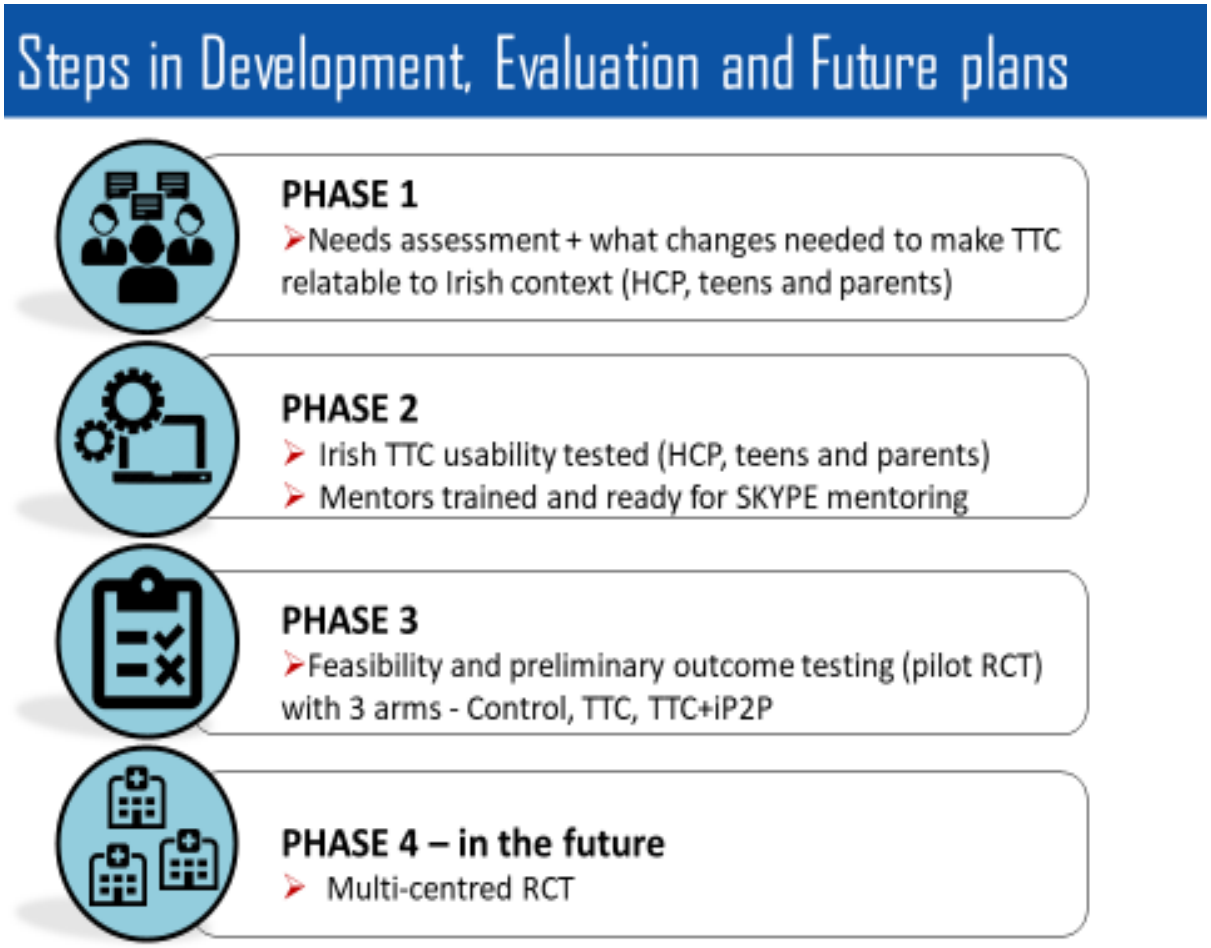

Figure 1: Development of pilot RCT and future for full RCT of Irish Teens Taking Charge and iPeer2Peer

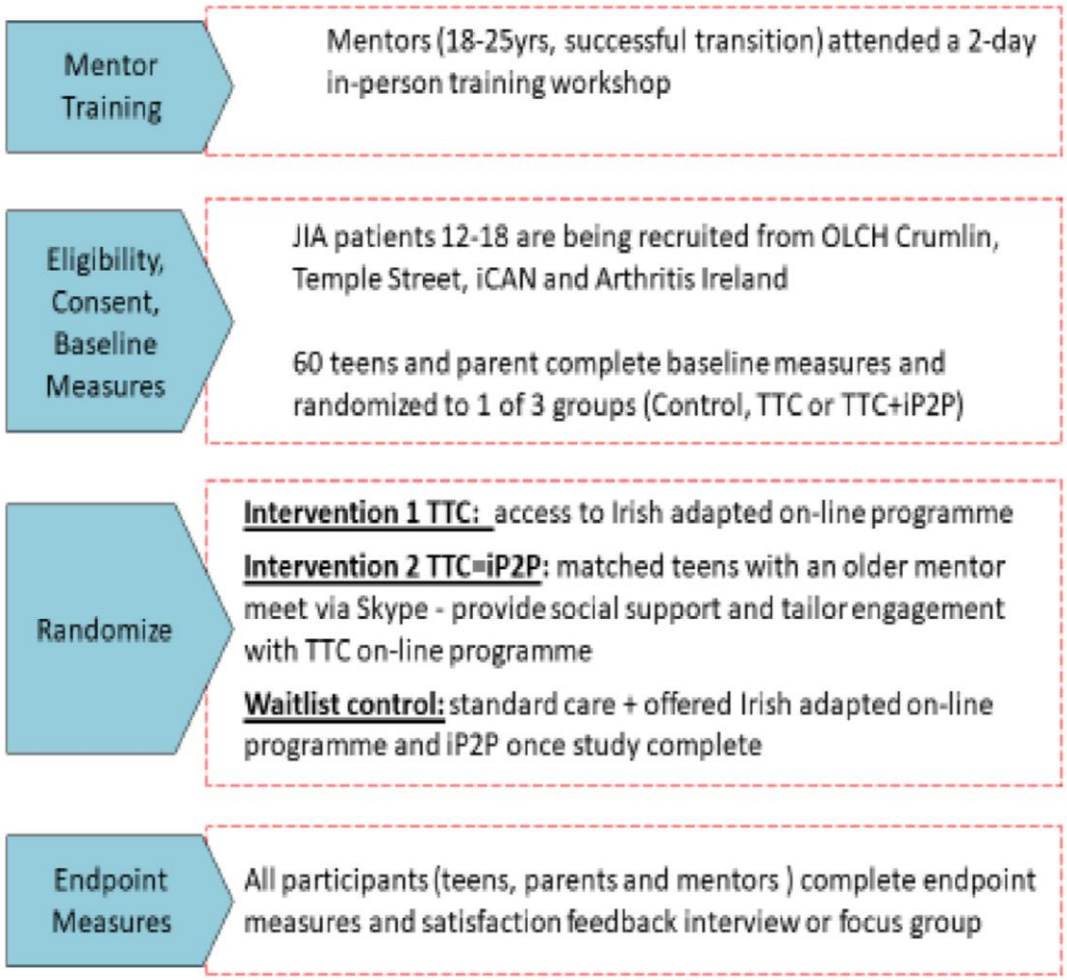

Figure 2: Schema of pilot RCT of TTC with iPeer2Peer

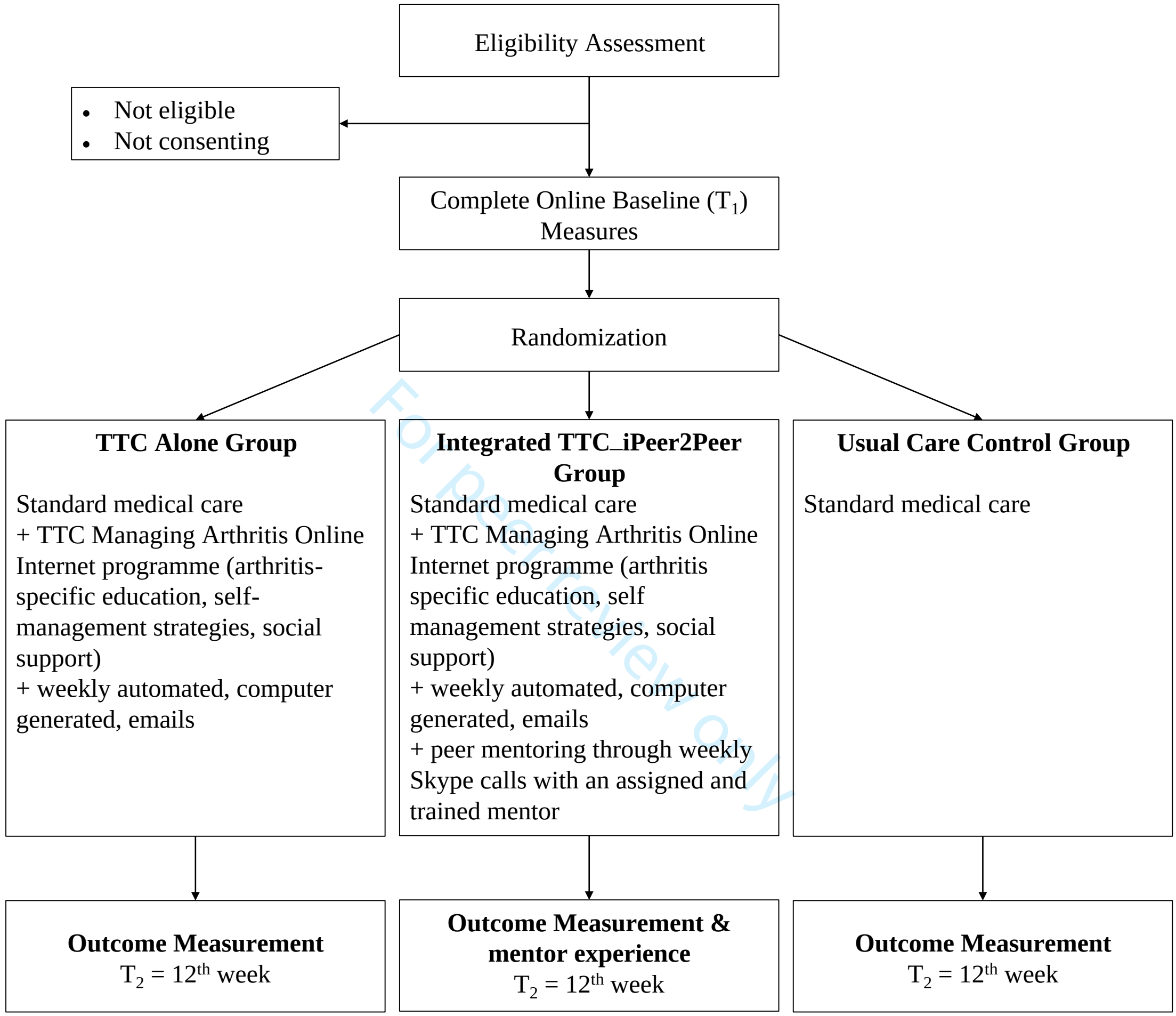

Figure 3: Flowchart of pilot RCT

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

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	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
Introduction			
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
Methods			
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

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

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological 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.

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	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2,17

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	
Funding	#4	Sources and types of financial, material, and other support	16
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1,16,17
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	2,17
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a

Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6-7
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-9

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	6,12,13
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-12
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9

Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	3,5,6,7
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8

Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-12
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12-13
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	1

Protocol amendments	#25	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
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	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
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a

Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	15-16
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a