

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	LENDING AN EAR: IPEER2PEER PLUS TEENS TAKING CHARGE ONLINE SELF-MANAGEMENT TO EMPOWER ADOLESCENTS WITH ARTHRITIS IN IRELAND. PROTOCOL FOR A PILOT RCT.
AUTHORS	O'Higgins, Siobhan; Stinson, Jennifer; Ahola Kohut, Sara; Caes, Line; Heary, Caroline; McGuire, Brian

VERSION 1 - REVIEW

REVIEWER	AUPIAIS University Paris Diderot, Site Villemin, Inserm, 75010 Paris, and Inserm, U1138, Equipe 22, Centre de Recherche des Cordeliers, 75006 Paris France
REVIEW RETURNED	04-Dec-2018

GENERAL COMMENTS	<p>The protocol presented in this document seems interesting. This pilot study aims at evaluating online interventions. Such online health interventions are increasingly used in various populations and diseases because of their efficacy. To adapt one to JIA in the Irish context seems important.</p> <p>However, this protocol is sometimes difficult to understand, especially for a non-Irish reader, and some points need to be clarified.</p> <p>General comments</p> <ul style="list-style-type: none">• The overall organization of the project is difficult to follow. Some part of the project have already be done (the Canadian TTC website's 3 basic components have been culturally adapted), the pilot study is the subject of the current paper, and a future RCT is planned. Please explain better that. I would have suggest to use a figure to represent the General framework / the different steps (obviously the step pf the pilot trial will be more developed).• Please also consider the use of the SPIRIT schematic diagram (http://www.spirit-statement.org/schedule-of-enrolment-interventions-and-assessments/)• The objectives are not congruent in abstract (To evaluate feasibility and preliminary outcome impact.... And to ensure the active involvement of adolescents.....) and in main paper (you specify only "To explore feasibility and preliminary effectiveness"). In my sense, the primary objectives of or a pilot trial should include
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at least : (i) To determine the feasibility of a full-scale RCT, (ii) to determine the sample size needed for the full-scale RCT.

- Likewise, objectives are sometimes not supported by Measures and/or Statistics and vice-versa. For example, cost effectiveness and cost utility analyses are planned. They do not answer to any of the objectives; and they are based on outcomes that are not described in the “measures” section.
- To help the reader, please define the abbreviations the first time they appear (HCP, RA,).

Specific comments

Title page

You should add the number of registration of the trial, and the date and version identifier of the plain protocol.

Abstract

- Please report the dates of recruitment
- Please report the planned sample size
- Objectives must be congruent with the manuscript

Introduction

- Please add precisions on the cultural differences between Canada and Ireland, because this is the most justification for this work.
- P3, line 46 “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”: Do you mean that such methods are not adapted to adults? Or it is not possible in adult services ?
- P4, What does mean HCP ?
- Is there any study evaluating an association between an online self management program and a peer review program ? (I mean different than TTC/iP2P in JIA or in others populations) If yes, what are the result?
- P4 line 45 “iP2P mentoring combined with TTC also has the potential to reduce the burden on services.”: Please justify
- Page 4 line 48: “Based on our qualitative need assessment, the Canadian TTC website's 3 basic components have been culturally adapted” :
 - Why only 3 basic components have been adapted ? (in the methods section you precise that the teens will received the “TTC intervention which consists of 12 modules”)
 - How this adaptation was made ?
 - What are the difference between Irish and Canadian version ?Please provide the new version as an annex.
- P5 line 31: Please explain what are Young People Advisory Panel as well as Arthritis Ireland (AI) and iCAN.

Methods

- P6 (Recruitment):
 - Can we expect patients recruited through the 3 different ways to be different ? If not, please justify. If yes, consider to stratify the randomisation.
 - Please report the dates of recruitment
 - This section needs to be more precise. Who will recruit and inform the participants? How the consent will be sought?
- P8-11 (measures)

	<ul style="list-style-type: none"> - Please define precisely all the measures, and who will assess the outcomes: please provide which outcomes are assessed online, which one are assessed through the semi-structured interviews, etc. i - P8 line 53: How will be rate the acceptability and satisfaction? - P11 line 39: How will you assess the comfort level with computers and the Internet • P12 (Data analysis): Be more precise for the statistical tests you plan to use (for binary outcomes and for continuous outcomes; anticipate the situation the normality of the data will not be ok) • P12 line 52: the SPIRIT reporting guidelines will not be useful to report the results, as these are guidelines for protocol.... You have to consider: (i) CONSORT 2010 statement: extension to randomised pilot and feasibility trials; (ii) Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 Extension; (iii) Standards for reporting qualitative research (SRQR) • P13 line 27: "at risk" for what ?
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REVIEWER	Enza D'Auria; M.D, PhD Department of Pediatrics Vittore Buzzi Children's Hospital University of Milan Italy
REVIEW RETURNED	28-Jan-2019

GENERAL COMMENTS	<p>The protocol for this pilot RCT is well designed and quite clearly presented. The aim of the study is very important and actual. I would the authors should address these points, as following:</p> <p>Introduction-Methods and Analysis:</p> <p>The authors state that a online questionnaire will be used: can add some details about this questionnaire?</p> <p>The diagnosis of arthritis relies on which criteria? The authors should explicit them</p> <p>Line 22 active involvement of all the stakeholder: which modalities for "active enrollment"? please, add some details</p> <p>Line 29: Inclusion criteria: "Adolescents between 12-18 years of age"; in the title appear "...to empower children with...: so, it is not clear which is the targeted population; children or adolescent? Please, clarify</p> <p>"description of study arm", Line 26: .."in addition to standard medical care": what standard medical care they exactly refer to? I suggest to explicit some of the treatments options (as in the standard clinical practice), also adding at least one or more references in the text and in the reference list, accordingly</p>
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VERSION 1 – AUTHOR RESPONSE

General comments

- The overall organization of the project is difficult to follow. Some part of the project have already be done (the Canadian TTC website's 3 basic components have been culturally adapted), the pilot study is the subject of the current paper, and a future RCT is planned. Please explain better that. I would have suggest to use a figure to represent the General framework / the different steps (obviously the step pf the pilot trial will be more developed).

- Please also consider the use of the SPIRIT schematic diagram (<http://www.spirit-statement.org/schedule-of-enrolment-interventions-and-assessments/>)
- The objectives are not congruent in abstract (To evaluate feasibility and preliminary outcome impact.... And to ensure the active involvement of adolescents.....) and in main paper (you specify only “To explore feasibility and preliminary effectiveness”). In my sense, the primary objectives of or a pilot trial should include at least : (i) To determine the feasibility of a full-scale RCT, (ii) to determine the sample size needed for the full-scale RCT.
- Likewise, objectives are sometimes not supported by Measures and/or Statistics and vice-versa. For example, cost effectiveness and cost utility analyses are planned. They do not answer to any of the objectives; and they are based on outcomes that are not described in the “measures” section.
- To help the reader, please define the abbreviations the first time they appear (HCP, RA,).

Specific comments

Title page

You should add the number of registration of the trial, and the date and version identifier of the plain protocol.

We have added the Trial registration number to page 2.

Abstract

- Please report the dates of recruitment
- Please report the planned sample size
- Objectives must be congruent with the manuscript

We have amended the abstract, with your suggestions.

The objectives in both abstract and manuscript have been modified and are now congruent.

Introduction

- Please add precisions on the cultural differences between Canada and Ireland, because this is the most justification for this work.

We have tried to ensure throughout the paper that the differences between the two countries' Health Care and support services and subsequent adaptations made to the text and with inclusion of Irish teens, parents and HCP videos are now highlighted to the reader.

- P3, line 46 “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”: Do you mean that such methods are not adapted to adults? Or it is not possible in adult services ?

This has been expanded to read that it is because they have to wait so long that they will most likely be in adult services before receiving CBT.

- P4, What does mean HCP ?

We have explained all the abbreviations throughout the paper.

- Is there any study evaluating an association between an online self management program and a peer review program ? (I mean different than TTC/iP2P in JIA or in others populations) If yes, what are the result?

To our knowledge is there not a study where peer mentors can use a specific on-line intervention to support their adolescent mentees and in so doing tailor the interaction with that intervention to meet the in-the moment needs of the adolescent participants. Although a very recent German paper evaluated cost-effectiveness of an Internet and mobile based intervention (IMI) where psychologists guided one arm of participants through the on-line intervention. Their analysis was looking at relative costs of guided versus unguided, as the ‘guides were not peers but psychologists (Paganini S, et al. A guided and unguided internet- and mobile-based intervention for chronic pain: health economic evaluation alongside a randomised controlled trial. *BMJ Open* 2019;9:e023390. doi:10.1136/bmjopen-2018-023390). Our cost effective analysis assess – according to the parents - costs of supporting their teen pre and post intervention.

- P4 line 45 “iP2P mentoring combined with TTC also has the potential to reduce the burden on services.”: Please justify

We have added in a sentence to explain why we believe this maybe the case (page 5).

- Page 4 line 48: “Based on our qualitative need assessment, the Canadian TTC website's 3 basic components have been culturally adapted” :

- Why only 3 basic components have been adapted ? (in the methods section you precise that the teens will received the “TTC intervention which consists of 12 modules”)

- How this adaptation was made ?

- What are the difference between Irish and Canadian version ? Please provide the new version as an annex.

- P5 line 31: Please explain what are Young People Advisory Panel as well as Arthritis Ireland (AI) and iCAN.

There are 3 components within TTC spread over the 12 modules.

See pages 5, 6 & 7 where we explain in brief the YPAP. Arthritis Ireland (page 3) and iCan (page 4) have also now been explained in the text.

Methods

- P6 (Recruitment):

- Can we expect patients recruited through the 3 different ways to be different? If not, please justify. If yes, consider to stratify the randomisation.

Different recruitment routes are being used in order to reach all eligible participants, as we cannot attend all clinics and a parent being given an invitation letter or there being a poster in the hospital may not ensure engagement with our study. We do not envisage the different routes reaching different types of participants, just different ways to raise their interest (page 8).

- Please report the dates of recruitment

We have been recruiting since January 2019 and will continue to do so until end of June. See pages 2 and 8.

- This section needs to be more precise. Who will recruit and inform the participants? How the consent will be sought?

We have added in more detail - See page 8

- P8-11 (measures)

- Please define precisely all the measures, and who will assess the outcomes: please provide which outcomes are assessed online, which one are assessed through the semi-structured interviews, etc.

p.11 we have added which measures will be assessed on-line etc.

- P8 line 53: How will be rate the acceptability and satisfaction?

p.10 this will assessed this through the semi-structured interviews.

- P11 line 39: How will you assess the comfort level with computers and the Internet

This is self- assessment – page 12

- P12 (Data analysis): Be more precise for the statistical tests you plan to use (for binary outcomes and for continuous outcomes; anticipate the situation the normality of the data will not be ok)

See page 13-14.

- P12 line 52: the SPIRIT reporting guidelines will not be useful to report the results, as these are guidelines for protocol.... You have to consider: (i) CONSORT 2010 statement: extension to randomised pilot and feasibility trials; (ii) Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 Extension; (iii) Standards for reporting qualitative research (SRQR)

We are now using the CONSORT Framework rather than SPIRIT as suggested.

In addition we have added two flowcharts to illustrate the process that brought us to the pilot RCT (Figure 1) and the pilot RCT (figure 2).

- P13 line 27: "at risk" for what ?

See page 14.

Reviewer: 2

Reviewer Name: Enza D'Auria; M.D, PhD

Institution and Country: Department of Pediatrics, Vittore Buzzi Children's Hospital, University of Milan, Italy

Please state any competing interests or state 'None declared':

None declared

Please leave your comments for the authors below

The protocol for this pilot RCT is well designed and quite clearly presented. The aim of the study is very important and actual. I would the authors should address these points, as following:

Introduction-Methods and Analysis:

The authors state that a online questionnaire will be used: can add some details about this questionnaire?

The questionnaire comprises of the measures as outlines in the method section pages 10-12

The diagnosis of arthritis relies on which criteria? The authors should explicit them

The diagnosis is based on criteria by HCP similar in Canada and Ireland. Detailing the tests and items used to measure and then diagnose the different types and severity of JIA would, we feel, be very onerous on the reader and not relevant to an understanding of our study.

Line 22 active involvement of all the stakeholder: which modalities for "active enrollment"? please, add some details .

I believe you refer to active involvement. See page 6 where we outline how we engage with YPAP and their parents through the study

Line 29: Inclusion criteria: "Adolescents between 12-18 years of age"; in the title appear ..."to empower children with...: so, it is not clear which is the targeted population; children or adolescent? Please, clarify

We have amended to be specific that this is about adolescents .

"description of study arm", Line 26: .."in addition to standard medical care": what standard medical care they exactly refer to? I suggest to explicit some of the treatments options (as in the standard clinical practice), also adding at least one or more references in the text and in the reference list, accordingly

see page 8 for additional information.