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Lending an ear: "iPeer2Peer" plus "Teens Taking Charge" Online Self-Management to empower children with arthritis

Submission date
01/10/2018

Recruitment status
Suspended

Registration date
04/02/2019

Overall study status
Completed

Last Edited
06/01/2021

Condition category
Musculoskeletal Diseases

- ☐ Prospectively registered
- ☒ Protocol
- ☐ Statistical analysis plan
- ☐ Results
- ☐ Individual participant data
- ☐ Record updated in last year

Plain English summary of protocol

Background and study aims
Juvenile Idiopathic Arthritis (JIA) negatively affects adolescents' everyday activities. JIA is the most common childhood rheumatic disease. In Ireland 1,200 children live with JIA, with over 100 children newly diagnosed annually, according to Arthritis Ireland (AI). Children and adolescents commonly experience a range of physical and emotional symptoms that limit physical and social interactions and negatively impact their health-related quality of life (HRQL). There is no cure, the disease course can be unpredictable, and HRQL deteriorates as the disease worsens. The Irish Paediatric Rheumatologist-to-patient ratio is the second lowest in Europe, with waiting lists of up to 2 years for medical intervention. Access to psychological support is equally limited in Ireland and, although cognitive-behavioural therapy (CBT) interventions can lead to improvement in pain and health-related quality of life (HRQL), most young people with JIA in Ireland will not receive these interventions due to various barriers to treatment. Internet-based interventions are a possible solution to address this gap between need, availability and access to effective treatments.Therefore, to address the need for effective, convenient, and affordable psychological self-management programmes, we developed an Irish version of the Canadian Teens Taking Charge (TTC): Managing JIA online programme and integrated it with Canadian skype-based peer support programme iPeer2Peer (iP2P).
Our Canadian colleagues have already evaluated the two programmes to be used 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 with 12 modules for teens and 2 for parents, with telephone support from a health coach (trained, adult non-health care professional without arthritis) for Canadian adolescents with JIA. Significant improvements were found in disease-related knowledge, decreased pain and increased exercise adherence. In addition to self management programmes, peer support given by another person with similar chronic illness is also associated with improved health outcomes. 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. Although TTC and iP2P have been positively evaluated separately by teens with JIA, these programmes have not been combined before.
We have already conducted a qualitative needs assessment with Irish members (teenagers and

parents) of two patient organisations: Arthritis Ireland (AI) and the Irish Children's Arthritis Network (iCAN). The needs assessment allowed us to explore the impact of JIA on adolescents and families, current services available in Ireland, and the value and usability of the Canadian TTC and iP2P programmes for an Irish population. Based on this need assessment, 3 basic components of the Canadian TTC website 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).

The main aim of this study will be to explore the usefulness and 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.

Who can participate?
Adolescents between the ages of 12-18 years who are living in Ireland and have a diagnosis of and are actively being treated forjuvenile idiopathic arthritis.

What does the study involve?
When a participant agrees to take part in the study, they will be randomly allocated to one of three groups. Group 1 will receive access to the TTC programme alone. Group 2 will receive access to the TTC programme and iP2P programme, therefore they will also be assigned a peer mentor who they will Skype with at least once a week. Group 3 will not receive access to TTC or iP2P programmes, however they will continue with their normal medical treatment. Participants in all groups will complete assessments before the intervention, immediately following intervention and at 3 months follow up.

What are the possible benefits and risks of participating?
By taking part, participants and their families will play a major role in the success of this project. It is only by carrying out studies like this that we can assess if the online programme, which was developed and tested in SickKids hospital in Toronto Canada, will positively support Irish adolescents with JIA and their families in coping with their chronic condition.
For adolescent participants themselves, the possible benefits include potential improvements in their self-management, disease knowledge, self-efficacy, physical pain, anxiety and depression, social support and quality of life after taking part in the intervention. However, a possible risk of taking part is that there is a potential for upset arising from exposure to questionnaires that ask about the impact of chronic health problems. The consent procedures being followed will minimise any risk to participant wellbeing and support will be recommended for any participant who experiences distress.

Where is the study run from?
Centre for Pain Research at the School of Psychology, NUI Galway (Ireland)

When is the study starting and how long is it expected to run for?
September 2017 to August 2020

Who is funding the study?
1. Health Research Board (HRB) (Ireland)
2. National Children's Research Centre (NCRC) (Ireland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NCHF-2017-003

Study information

Scientific Title
Lending an ear: "iPeer2Peer" plus "Teens Taking Charge" Online Self-Management to empower children with arthritis

Study objectives
1. Adolescents will find the integrated iPeer2Peer-Teens Taking Charge (TTC) acceptable and there will be a difference in engagement, tailoring and dropout rate between adolescents randomised to the integrated iPeer2Peer-TTC group compared to those randomised to TTC alone group
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
3. There will be differences (comparing scores before and after intervention) in disease knowledge, self-efficacy, physical (pain) and emotional (anxiety, depression) symptoms, perceived social support, Health Related Quality of Life (HRQL) post-treatment in adolescents

with JIA who are randomized to the integrated iPeer2Peer-TTC group compared to those who are randomized to TTC alone or treatment as usual (control) group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee at National University of Ireland, Galway, 13/12/2017, reference: 'NUI Galway Research Ethics Committee 17-Nov-10'

Study design
Interventional single-blinded three-armed pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Juvenile idiopathic arthritis

Interventions
Participants 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. The experimental groups will be TTC alone and iP2P-TTC combined. The control group will receive treatment as usual.
In addition to standard medical care, participants in the TTC alone group will receive an 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 a restricted password-protected website that allows the team to track usage. The TTC programme is set up in a modular fashion, which 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 with missed modules (e.g. due to feeling unwell, exams, holidays etc).
Participants in the iP2P-TTC combined experimental group will also have access to TTC in the same format as described above for the TTC alone group. In addition to this, participants in this group will be matched with a peer mentor. Peer mentors will be young people who have a diagnosis of juvenile idiopathic arthritis (JIA) and are successfully managing their JIA. Mentors

will be identified by a health care professional (HCP) or the support groups (Arthritis Ireland and ICAN). Mentors will complete 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 mentor will have. However, we will advise weekly contact. The aim will be for a maximum of 12 calls within a 15-week period. Mentors will be supported throughout the duration of the study through regular consultations with research staff via email and/or Skype. Additional training in mentorship skills may be provided if required.
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.
The control group will receive their usual healthcare appointments, medication and therapies over the 15-week period. The control group will not receive access to either TTC or iP2P programmes during their participation.

Intervention Type
Behavioural

Primary outcome measure
1. Acceptability and satisfaction of the intervention, assessed by:
1.1. Adolescents with JIA and their parents in the TTC and iP2P-TTC intervention groups will rate acceptability of and satisfaction with the intervention immediately post-intervention using a questionnaire designed specifically for this intervention
1.2. Semi-structured interviews at study completion with 4-6 adolescent-parent dyads (chosen using a random number list), to assess satisfaction with TTC and the integrated iP2P-TTC programme
1.3. Semi-structured interviews with the adolescents post-intervention to broadly assess engagement (including the most helpful aspects, participant enjoyment and how the tailoring was done)
2. Quality of received mentorship (for participants allocated to the integrated iP2P-TTC group only), assessed using the Mentor Behaviour Scale (MBS) immediately following completion of the intervention
3. Perspectives of mentors explored the mentoring experience with the following methodology:
3.1. Individual semi-structured telephone interviews conducted before the mentors commence the mentoring programme (to gauge their expectations)
3.2. 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.
3.3. Individual 'data-prompted' interviews conducted face-to-face once the mentoring programme is complete.
4. Website programme usage (which TTC modules have been accessed and in what order) by adolescents with JIA and parents in the TTC alone group, tracked by Google Analytics throughout the study
5. Usage of the iP2P-TTC intervention for the iP2P-TTC group:
5.1. Order and amount of used TTC modules, tracked by Google Analytics throughout the study
5.2. Number and length of calls with mentor and discussed topics with mentors. Mentors will complete an online questionnaire after each Skype session, where they will enter the date of the Skype session, the module discussed and specific topics discussed during the session. Skype calls will be recorded by the mentors and sent to the research team following each Skype session, and the length of time and module discussed will be recorded by the research team to ensure the mentor is recording the information correctly.

Secondary outcome measures

The following will be assessed at the baseline, immediately post-intervention and at the 3 and 6 month follow-up for adolescent participants:
1. Self-management, assessed using TRANSITION-Q
2. Disease knowledge, assessed using the Medical Issues, Exercise, Pain and Social Support Questionnaire (MEPS)
3. Self-efficacy, assessed using the Children's Arthritis Self-Efficacy (CASE) questionnaire
4. Physical pain, assessed using the PROMIS Pediatric Profile Pain Intensity and Interference scales
5. Emotional symptoms (anxiety and depression), assessed using the PROMIS Pediatric Profile Anxiety and Depression scales
6. Perceived social support, assessed using the PROMIS Pediatric Profile Peer Relationship Scale
7. Health-related quality of life, assessed using the PedsQL Arthritis Module

The following will be assessed at the baseline, immediately post-intervention and at the 3 and 6 month follow-up for parents regarding their adolescents:
1. Health-related quality of life, assessed using the PedsQL Arthritis Module
2. Adherence, assessed using the Patient Adherence Report Questionnaire (PARQ)
3. Medical issues, assessed using the Medical Issues Questionnaire
4. Self-efficacy, assessed using the Parent Arthritis Self-Efficacy (PASE) Scale

The following will be assessed at the baseline, immediately post-intervention and at the 3 and 6 month follow-up for the mentors:
1. Perceived ability to perform one's usual social roles and activities, assessed using the Ability to Participate in Social Roles and Activities - PROMIS Short Form 8a
2. Disease self-efficacy, assessed using the Chronic Disease Self-Efficacy Scale
3. PROMIS–29 Profile v2.0.19, a five-point scale assessing the following areas:
3.1. Physical function (4 items)
3.2. Anxiety (4 items)
3.3. Depression (4 items)
3.4. Fatigue (4 items)
3.5. Sleep disturbance (4 items)
3.6. Ability to participate in social roles and activities (4 items)
3.7. Pain interference (4 items)
3.8. Pain intensity on a scale of 1-10 (1 item)

The following outcome measures will be assessed at the baseline, immediately post-intervention and at 3-month follow-up for adolescent participants:
1. Self-management, assessed using TRANSITION-Q
2. Disease knowledge, assessed using the Medical Issues, Exercise, Pain and Social Support Questionnaire (MEPS)
3. Self-efficacy, assessed using the Children's Arthritis Self-Efficacy (CASE) questionnaire
4. Physical pain, assessed using the PROMIS Pediatric Profile Pain Intensity and Interference scales
5. Emotional symptoms (anxiety and depression), assessed using the Revised Children’s Anxiety and Depression Scale (RCADS) - 25 items, with subscale scores for depression and anxiety as well as an overall internalising score.
6. Perceived social support, assessed using the PROMIS Pediatric Profile Peer Relationship Scale
7. Health-related quality of life, assessed using the PedsQL Arthritis Module

The following will be assessed at the baseline, immediately post-intervention and at 3-month follow-up for parents regarding their adolescents:
8. Health-related quality of life, assessed using the PedsQL Arthritis Module

9. Adherence, assessed using the Patient Adherence Report Questionnaire (PARQ)
10. Medical issues, assessed using the Medical Issues Questionnaire
11. Self-efficacy, assessed using the Parent Arthritis Self-Efficacy (PASE) Scale
12. Health Services Use and Out-of-Pocket Expense Diary assessing 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.

The following will be assessed at the baseline, immediately post-intervention and at 3-month follow-up for the mentors:
13. Perceived ability to perform one's usual social roles and activities, assessed using the Ability to Participate in Social Roles and Activities - PROMIS Short Form 8a
14. Disease self-efficacy, assessed using the Chronic Disease Self-Efficacy Scale
15. PROMIS–29 Profile v2.0.19, a five-point scale assessing the following areas:
15.1. Physical function (4 items)
15.2. Anxiety (4 items)
15.3. Depression (4 items)
15.4. Fatigue (4 items)
15.5. Sleep disturbance (4 items)
15.6. Ability to participate in social roles and activities (4 items)
15.7. Pain interference (4 items)
15.8. Pain intensity on a scale of 1-10 (1 item)
16. iPeer2Peer Mentor Training Evaluation 5 point scale, 10 items
17. The mentoring experience will be explored with the following methodology:
17.1. Individual semi-structured telephone interviews conducted before the mentors commence the mentoring programme (to gauge their expectations)
17.2. 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.
17.3. Individual 'data-prompted' interviews conducted face-to-face once the mentoring programme is complete.

Overall study start date
01/09/2017

Completion date
31/08/2020

Eligibility

Key inclusion criteria
Adolescent (mentee):
1. Aged 12-18 years
2. Diagnosed with and actively being treated for JIA (any subtype)
3. Parent and adolescent are both able to speak and read English.
4. Access to a computer/ smartphone and internet connection

Mentor:
1. Aged 18-26 years

2. Diagnosis of JIA (any subtype)
3. Nominated by a member of their health care team as a good mentor
4. Self-reported adherence to current treatment plan (80-100% compliance)
5. Self-reported successful transition to an adult rheumatologist
6. Self-reported self-efficacy in their ability to manage their JIA related symptoms
7. Willingness to commit to training (20 hours) and mentoring participants (once paired with mentee 10 to 30 minute calls over a period of 15 weeks)
8. Access to a computer/ smartphone and internet connection

Young person advisory panel:
1. Aged 12-18 years
2. Diagnosis of JIA (any subtype)
3. Nominated by a member of their health care team as a good mentor
4. Access to a computer and internet connection
5. Self-reported self-efficacy in their ability to manage their JIA related symptoms
6. Willingness to commit to training (20 hours) and mentoring participants (once paired with mentee 10 to 30 minute calls over a a period of 12 weeks)

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Minimum of 60

Key exclusion criteria
Adolescent (mentee), peer mentor and young person advisory panel member:
1. Major cognitive impairments,
2. Co-morbid medical or psychiatric illnesses based on medical assessment which may impact on ability to understand and use web-based programmes

Parents/caregivers will not be eligible to participate in the study alone (without an adolescent also participating)

Date of first enrolment
01/10/2018

Date of final enrolment
01/06/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Centre for Pain Research
School of Psychology, NUI Galway. Co. Galway
Galway
Ireland
H91 EV56

Sponsor information

Organisation
Health Research Board

Sponsor details
Grattan House
67-72 Lower Mount Street
Dublin
Ireland
D02 H638

Sponsor type
Government

Website
http://www.hrb.ie/

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan

Dissemination of results will be via journal articles, conference presentations by researchers and stake holders, and the launch of an accessible, effective and sustainable Internet self-management and peer support intervention for Irish adolescents with JIA.

Intention to publish date

31/08/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Judith Burke via email at judith.burke@nuigalway.ie. The data will become available from 01/08/2020, in the form of quantitative and qualitative analyses results. The research team, consisting of the Principle Investigator, postdoctoral researcher, and the research assistant will have access to participant data. Qualitative data collection exploring the mentor experience will be conducted by an additional researcher, therefore, this researcher will have access to the mentor qualitative data only.
Data will be kept confidential and anonymous by using subject code numbers, as well as by storing all raw data forms in a locked filing cabinet in the principal investigator's office (locked) at NUI Galway. Consent and assent forms will be kept as per institutional policies and then shredded. Finally, participants will be assured that study reports, audiotapes (de-identified), and questionnaires will contain no identifying information in keeping with privacy legislation.
A number of measures will be taken to protect the rights of eligible participants, including:
1. Using an intermediate approach (neutral HCP such as a nurse or social worker) to gain initial permission to approach potential participants about the study
2. Ensuring anonymity, privacy and confidentiality of personal information
3. Proceeding through formal ethical review processes at the participating hospital and university. All information obtained during the study will be treated with confidentiality; allmembers of the research team have experience handling confidential, patient information. The person transcribing the interviews will sign a contract to protect privacy and ensure confidentiality of audiotapes (all tapes will be de-identified prior to transcribing them).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	15/12/2019	06/01/2021	Yes	No