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Development and evaluation of an online version of the Feeling Better pain management programme for children and their caregivers

Submission date
18/03/2019

Recruitment status
No longer recruiting

Registration date
25/03/2019

Overall study status
Completed

Last Edited
23/04/2021

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There is promising evidence that Internet-delivered treatments may be beneficial for children and adolescents with chronic pain. Little is known about the acceptability of technology-based psychological treatment for early school age children (age 5-12 years) with chronic pain. The online Feeling Better programme is an accessible source of support for children with chronic pain and their caregivers. The programme is designed to improve perceived competence in pain self-management and participant use of active coping strategies for pain management. The main aim of this study is to assess the feasibility of carrying out a full trial of the Feeling Better programme.

Who can participate?
Children aged between 5-12 years with any type of chronic or persistent pain (pain which has lasted for three months or more) and their caregiver(s)

What does the study involve?
Children with chronic pain and their caregivers are screened and randomly allocated to one of two groups (Internet intervention or waitlist control group). Those assigned to the Internet intervention are asked to complete a nine-week, online cognitive behaviour therapy programme called Feeling Better. The Feeling Better programme features 9 sessions. Participants are asked to complete one session per week. Each weekly session is designed to last about 30 minutes and focuses on a different theme and range of coping skills. Children and caregivers who agree to take part are asked to complete an online assessment measuring pain intensity, physical limitations and well-being before taking part, post-treatment and at 3-month follow-up.

What are the possible benefits and risks of participating?
Children and parents who take part may benefit from access to a free online source of support and information relating to chronic pain management. Further benefits may follow from training in cognitive behaviour therapy techniques specifically tailored for chronic pain management and for school-age children.

Where is the study run from?
The Feeling Better study takes place online: https://www.feelingbetter.ie. The study is managed by researchers at the School of Psychology, National University of Ireland Galway

When is the study starting and how long is it expected to run for?
July 2013 to April 2017

Who is funding the study?
This work is funded by a Hardiman Postgraduate Research Scholarship awarded by the Galway University Foundation, National University of Ireland Galway.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
-

Study information

Scientific Title
Development and evaluation of an online version of the Feeling Better pain management programme for children and their caregivers

Acronym
Feeling Better

Study objectives
Children participating in the Feeling Better programme will show greater improvement in symptoms and modification of maladaptive pain cognitions compared to children in a waitlist control condition. These improvements will be maintained in children receiving the Internet intervention at the 3-month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/01/2014 by Research Ethics Committee at National University of Ireland Galway, Research Office, Research and Innovation Centre, National University of Ireland Galway, University Road, Galway, H91 TK33, Ireland, Tel: +353 (0)91 495312, Email: vpresearach@nuigalway.ie, ref: 13/ Nov/01

Study design

Interventional randomised controlled feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Any type of paediatric chronic pain

Interventions
Assessments are completed independently by children and parents at baseline before randomization, upon completion of the 9-week intervention and at a three-month follow-up period. Varying block allocation ratios are used. Following an online baseline assessment, participants are randomly allocated to either the online Feeling Better programme or a waitlist control condition. Ideally, approximately 30 participants will be randomised to each intervention condition. The online Feeling Better programme involves weekly, online cognitive behaviour therapy based pain management sessions for children and caregivers over 9 weeks. Participants are asked to complete one session per week. Each weekly session is designed to last approximately 30 minutes and focuses on a different theme and range of coping skills.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility and clinical outcome assessments were carried out at baseline (T1), at post-treatment (T2, 9-11 weeks) and at three-month follow-up (T3).

The primary feasibility outcome measures for this study are:
1. Recruitment measured by the percentage of eligible participants who progressed from initial enquiry to treatment allocation and enrolment.
2. Retention to follow-up measured by the completeness of online data collection in each arm at post-intervention and 3- month follow-up. This will be presented as a percentage of the participants randomised.
3. Treatment compliance measured at 9-11 weeks post-randomisation by means of objective system usage data ('participant access data'). Website use and treatment engagement were measured in the following ways:
3.1. The number of sessions completed (0-18 total) . treatment compliance)
3.2. The number of times users logged in ('unique logins')
3.3. The average length of time users remained logged in
3.4. The number of times individual pages were viewed
3.5. The number of interactive strategies completed
3.6. The number of participants who submitted weekly homework
3.7. The most and least accessed website components based on the module page accessed and completion rates
4. Treatment satisfaction and acceptability measured using the Internet Evaluation and Utility Questionnaire (Thorndike et al., 2008). This measure was used at T2 / post-intervention only.
5. Website satisfaction measured using six purposely constructed questions based on Ritterband' s model for intervention development (Ritterband et al., 2009). This measure was used at T2 / post-intervention only.

6. Treatment expectancies: post-randomisation, children and parents completed a measure of treatment expectancies which comprised of a visual analogue scale with anchors (0 = No help, 10 = Most help you can imagine) that asked participants to select the face and numerical anchor which shows how much they anticipate this programme might help with symptom improvement. This measure was used at T1 / baseline assessment only.

The primary clinical outcome measures for this study are:
1. Physical health (functional limitations) assessed using the Pediatric Quality of Life Inventory - Physical health subscale (PedsQL™ 4.0; Varni, 1998). This measure was used at each point of assessment for the intervention group and at baseline and post-intervention for the control group.
2. Pain intensity assessed using the Wong-Baker FACES Pain Rating Scale, a sixitem ordinal faces scale (WBS) which assessed the intensity of pain from none to worst in the previous two weeks. This measure was used at each point of assessment for the intervention group and at baseline and post-intervention for the control group.

Key secondary outcome(s))

Feasibility and clinical outcome assessments were carried out at baseline (T1), at post-treatment (T2, 9-11 weeks) and at three-month follow-up (T3).
1. Mood assessed by children and parents using the Pediatric Quality of Life Inventory – psychological health subscale-(PedsQL™ 4.0; Varni, 1998). This measure was used at each point of assessment for the intervention group and at baseline and post-intervention for the control group.
2. Child health-related quality of life assessed using the Pediatric Quality of Life Inventory - (PedsQL™ 4.0; Varni, 1998). This measure was used at each point of assessment for the intervention group and at baseline and post-intervention for the control group.
3. Child use of strategies to cope with pain measured using the Pediatric Quality of Life Inventory – Coping Skills Inventory (PedQL-CSI; Varni, 1996). This measure was used at each point of assessment for the intervention group and at baseline and post-intervention for the control group.
4. Level of catastrophizing assessed with the Pain Catastrophising Scale-Child and Parent versions (PCS-C&P; Crombez et al., 2003). This measure was used at each point of assessment for the intervention group and at baseline and post-intervention for the control group.
5. Pain-related self-efficacy assessed using the Self-efficacy for Functioning Despite Pain Scale – Child and Parent report (Bursch et al., 2006). This measure was used at each point of assessment for the intervention group and at baseline and post-intervention for the control group.
Levels of parental protective behaviour assessed using the Adult Response to Children's Symptoms–Protect Subscale- child and parent versions (Walker, Ley & Whitehead, 2006). This measure was used at each point of assessment for the intervention group and at baseline and post-intervention for the control group.
6. Socio-demographic characteristics and condition-specific background information for the participants in each arm of the trial were recorded at baseline to determine if there were any inequalities across groups in terms of uptake, randomisation, compliance and retention. This data included age, sex, ethnic group, marital status, highest level of educational attainment, pain type and duration.
7. Adverse events: Participants were asked to respond to an open-ended question concerning potential adverse events occurring during the study at post-intervention and follow-up assessment.

Completion date

17/04/2017

Eligibility

Key inclusion criteria
1. Aged age 5 to 12 years
2. Experienced chronic or recurrent non-malignant pain present for a period of 3 months or more which met the criteria for a diagnosis of chronic or recurrent pain as defined by the International Association for the Study of Pain (IASP, 1986)
3. Experienced pain at least once per week
4. Experienced pain interference in at least one area of daily functioning as per parent report
5. Could read and write English
6. Had regular access to a computer with an Internet connection
7. Agreed not to engage in psychological treatment for chronic pain management during the active phase of participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
1. The child had a serious psychiatric illness
2. The child had pain associated with a chronic medical condition (e.g. cancer)
3. The child had a developmental disability which would prevent them understanding the research materials
4. The parent or child was non-English speaking
5. The family did not have regular access to the Internet on a computer or portable device e.g. tablet or laptop computer

Date of first enrolment
05/01/2016

Date of final enrolment
05/01/2016

Locations

Countries of recruitment

United Kingdom

Canada

Ireland

United States of America

Study participating centre
National University of Ireland Galway
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Sponsor information

Organisation
National University of Ireland Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
University/education

Funder Name
National University of Ireland, Galway

Alternative Name(s)
Coláiste na hOllscoile, Gaillimh, Ollscoil na hÉireann Gaillimh, Queen's College, Galway, University College, Galway, NUI Galway, National University of Ireland, Galway, National University of Ireland Galway, Ollscoil na Gaillimhe, National University of Ireland, Galway/NUI Galway, NUI Galway, OÉ Gaillimh

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
Online, written consent was obtained from parent participants and written assent was obtained from child participants who were willing to participate. In line with the code of ethics governing this research, participants were reminded of the voluntary nature of the participation, about their right to withdraw at any time and that their data would be stored securely and anonymously in accordance with the Data Protection Act (1990).
Questionnaire data was saved online using a LimeSurvey platform embedded within the intervention website. This data was automatically anonymised and stored separately i.e. in a separate database to the intervention content data (i.e. separate to user input into the website). All data was stored using industry standard protection and encryption procedures. Participant data was only accessible by the first author. When collated, this data was stored in encrypted virtual hard-drives, in both .csv and .sav file formats and made accessible to the trial supervisors (Prof Brian McGuire and Dr. Jonathan Egan). This data will be retained for a period of 5 years in accordance with the NUI Galway data retention policy. Adult consent and child assent was obtained prior to data collection. All participants consented to the use of this data for the purpose of this research.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes
Thesis results			23/04/2021	No	No