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Assessing the effectiveness of the Feeling Better ASD pain management program for autistic children

Submission date
23/09/2024

Recruitment status
No longer recruiting

Registration date
11/11/2024

Overall study status
Ongoing

Last Edited
24/07/2025

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Self-reporting pain is seen as the 'gold standard' in pain assessment and management. However, self-report measures are not always accessible or feasible for use with autistic individuals, who may often find it difficult to communicate pain and may express their pain in “atypical” ways such as changes in behaviour. As a result, pain may be unrecognised and untreated. This can have a significant impact on the individual experiencing pain. The purpose of this study is to provide education for autistic children and their parents by teaching the skill of communicating pain and also learning skills and techniques such as relaxation, activity pacing, and distraction skills to help them cope with pain using the Feeling Better ASD pain management programme.

Who can participate?
Autistic children with or without co-occurring intellectual disability, aged between 5-17 years, who experience recurrent or chronic pain (pain lasting more than 3 months).

What does the study involve?
Participants are given 2 weeks to decide whether they would like to take part in this research. Participants will be asked to complete a consent form. After consent is provided participants will be assigned at random by the researchers to one of the two groups: the Internet Intervention Condition [i.e. Feeling Better-ASD] (Group A) or the Waitlist Control Condition (Group B). Each participant will be assigned an ID number. The researchers will use a random number generator to assign each participant to one of the two groups. Before beginning the programme, parents will be asked to complete a questionnaire about their child’s current pain and functioning. This questionnaire is completed before and after the programme to examine whether the Feeling Better ASD programme has been helpful in supporting their child to communicate pain and learn skills to help cope with their pain.

INTERNET INTERVENTION (GROUP A):
Participants assigned to ‘Internet Intervention (Group A) will take part in the Feeling Better ASD programme immediately. The programme has 13 "missions" or modules which have been designed to provide educational information for autistic children to communicate and cope with

their pain. Each mission will involve information about understanding pain, the communication of pain and strategies to cope with pain. Participants will be asked to complete one module each week. Each module will take approximately 20-25 minutes to complete. Each day participants will be asked to record their pain in a 'pain diary'. This takes about 5 minutes to complete. Each day participants will record if they had pain, the location of their pain (using a body map), and report 'how they are feeling' (using a visual pain scale). This pain diary is to support participants in communicating when they have pain. The programme will be delivered using a secure website protected by encryption. Participants will engage in skills practice throughout each of the modules. Each mission will provide resources that can be accessed online or ready to print.

WAITLIST CONTROL (GROUP B):
Participants assigned to the 'Waitlist Control (Group B)' will not initially have access to the Feeling Better ASD programme. Participants will be asked to complete a questionnaire at the beginning and again at the end of a 13-week period. The questionnaire will take about 20 minutes to complete. When the second questionnaire has been completed, after a period of approximately 13 weeks, participants will then be invited to take part in the Feeling Better ASD programme. Everyone who registers for this study will have the opportunity to access the Feeling Better ASD pain management programme. Upon completing the Feeling Better ASD programme, participants will be asked to complete a final questionnaire.

What are the possible benefits and risks of participating?
The aim of this research is to provide education for participants by teaching the skill of communicating pain and also learning skills and techniques such as relaxation, activity pacing, and distraction skills to help them cope with pain using the Feeling Better ASD pain management programme.
Taking part in this research will provide access to educational materials that aim to support and increase the communication of pain and coping strategies for participants. Each mission within the programme will include useful resources (visual pain scale, communication visuals and individualised materials) that aim to encourage the communication of pain and coping techniques which participants can use when they experience pain.
Each participant will have access to the online programme with a unique username and password.
This study will involve participants discussing their pain and learning strategies to communicate and cope with pain. There is a small risk that participants may find some of the content within the programme distressing, as they relate to their experiences of pain. Contact details of helplines are provided if participants become distressed. Participants can also contact members of the research team for advice and support if required. At any time if participants wish to stop participation in this research they can do so without giving any reason.

Where is the study run from?
The study is being led by researchers at the School of Psychology at the University of Galway. The researchers are members of the Centre for Pain Research and the Applied Behaviour Research Clinic.

When is the study starting and how long is it expected to run for?
July 2022 to May 2026

Who is funding this study?
This research is being conducted by the principal investigator, Rachel Fitzpatrick, PhD student in the School of Psychology at the University of Galway. This research is being supervised by Dr.

Helena Lydon and Prof. Brian McGuire. The research team are members of the Applied Behaviour Research Clinic (ABRC), and The Centre for Pain Research (CPR) at the University of Galway. The research is not funded by an external agency.

Who is the main contact?
Rachel Fitzpatrick, r.fitzpatrick7@universityofgalway.ie

Supervisors:
Dr Helena Lydon, helena.lydon@universityofgalway.ie
Prof. Brian McGuire, brian.mcguire@universityofgalway.ie

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Ms Rachel Fitzpatrick

Contact details
School of Psychology
University of Galway
Galway
Ireland
H91 TK33
+353 (0)91 524 411
r.fitzpatrick7@universityofgalway.ie

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the Feeling Better ASD pain management pain management programme for autistic children: a pilot and feasibility study

Acronym
Feeling Better ASD

Study objectives
The primary aim is to evaluate the feasibility and preliminary efficacy of the Feeling Better ASD program for autistic children aged 5-17 years who experience recurrent or chronic pain.

1. Children receiving the Feeling Better ASD programme will show an increase in pain communication skills and use of pain coping strategies compared to children in a waitlist control condition.
2. The Feeling Better ASD programme will show evidence of feasibility (usability, acceptability and satisfaction) as demonstrated by high rates of completion of programme content, low attrition and high levels of participant and parent satisfaction with the programme upon completion.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/02/2023, Research Ethics Committee (University of Galway, Galway, T91 TK33, Ireland; +353 (0)91 493757; ethics@universityofgalway.ie), ref: 2023.02.007

Study design
Randomized pilot and feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Information sheet can be found here: https://www.universityofgalway.ie/abrc/research/

Health condition(s) or problem(s) studied
Chronic or recurrent pain in children aged 5-17 years with autism spectrum disorder

Interventions
Participants will be asked to complete a consent form. After consent is provided participants will be assigned at random by the researchers to one of the two groups: the Internet Intervention Condition [i.e. Feeling Better-ASD] (Group A) or the Waitlist Control Condition (Group B). Each participant will be assigned an ID number. The researchers will use a random number generator to assign each participant to one of the two groups.

The intervention consists of a 13-week online programme that focuses on increasing pain communication and coping strategies in autistic children aged between 5-17 years. There are 13 modules ("missions") within the programme. Four key skills are taught in the programme:
1. Understanding pain

2. Pain communication
3. Pain management
4. Anxiety and pain.

Each mission will focus on teaching a key skill in pain communication and pain management. The Feeling Better ASD pain programme will focus on providing education for autistic children by teaching the skill of communicating pain and coping strategies such as relaxation, activity pacing and distraction skills to help them cope with pain.

Prior to engaging in the programme, parents are required to complete a pre-test questionnaire. Participants (children) are also required to complete one question (self-report) about their pain. Once the pre-test is completed, participants commence the programme.

Each week, participants are required to complete one mission in the programme. Each mission takes approx. 20 minutes to complete. After completion of the mission, participants are asked to complete a pain diary for each day until the next mission is made available (missions released at the start of each week). Participants can report their experience of pain using the Wong-Baker FACES Pain Scale, a body map to identify the location of their pain and can list any pain management strategies they engaged in that week to help cope with pain. Weekly check-ins will be conducted with each participant's parent via email or phone call.

Post-test questionnaires will be completed after participants have completed the programme. This is to examine if there were any changes from baseline on the patient-centred measures.

Intervention Type
Behavioural

Primary outcome measure
1. Pain communication (frequency) measured using structured questions at baseline and post-intervention (13 weeks)
2. Pain-coping strategies (frequency) measured using the PedsQL Coping Skills Inventory at baseline and post-intervention (13 weeks)

The primary feasibility outcome measures for this study are:
1. Recruitment and retention rates measured from the programme database post-intervention
2. Treatment engagement: the number of missions completed, the number of times participants logged in, the average length of time participants logged in, the number of times individual pages were viewed, the number of interactive activities completed, the number of participants who completed the daily pain diary, the most and least accessed programme components based on the mission page accessed and completion rates measured from the programme database post-intervention
3. Programme satisfaction measured at post-test using open-ended programme-specific questions referring to theme, navigation, intensity, interactive features, ease of use and level of researcher contact. Also, participants are asked to rate experience satisfaction on a 5- 5-point Likert scale ranging from 0 (not at all) to 4 (very) at post-test.
4. Treatment expectancy measured using a 5-point Likert scale at baseline and post-intervention
5. Treatment acceptability and satisfaction measured using the Internet Evaluation and Utility Questionnaire at post-test

Secondary outcome measures

1. Clinical outcomes measured at baseline and post-intervention:
1.1. Pain intensity measured using a visual analogue scale (VAS) at baseline and post-intervention (13 weeks). Parents respond to four questions. The child completes one self-report question at baseline and post-intervention (13 weeks)
1.2. Pain interference with daily living measured using the Child Activity Limitations Interview-21 (parent version) at baseline and post-intervention (13 weeks)
1.3. Overall well-being measured using the PedsQL General Well-Being Inventory (parent version) at baseline and post-intervention (13 weeks)
1.4. Parental protectiveness measured using the Adult Responses to Children's Symptoms ARCS, protect sub-scale at baseline and post-intervention (13 weeks)
1.5. Pain catastrophizing measured using the Pain Catastrophizing Scale (parent version) at baseline and post-intervention (13 weeks)
2. Adverse events measured through five questions completed by parents at post-intervention (13 weeks), reporting on any adverse events across the study period
3. Parents' and participants' beliefs about the overall/global efficacy of the intervention measured using the Global Impression of Change (three questions) at baseline and post-intervention (13 weeks)
4. Programme usage data measured from the programme database post-intervention

Overall study start date
01/07/2022

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Children aged between 5-17 years with a diagnosis of Autism Spectrum Disorder (ASD) with or without co-occurring intellectual disability
2. Experience chronic or recurrent pain for a period of 3 months as defined by the International Association for the Study of Pain (IASP, 2019)
3. Sufficient command of English to complete the programme and outcome measures
4. Able to provide consent/assent
5. Access to a computer/iPad with an internet connection

Participant type(s)
Patient, Carer, Other

Age group
Child

Lower age limit
5 Years

Upper age limit
17 Years

Sex

Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. People with sensory impairment that would prevent participation

Date of first enrolment
01/10/2024

Date of final enrolment
30/03/2025

Locations

Countries of recruitment
Ireland

Study participating centre
University of Galway
University Road
Galway
Ireland
H91 TK33

Sponsor information

Organisation
Ollscoil na Gaillimhe – University of Galway

Sponsor details
University Road
Galway
Ireland
H91 TK33
+353 (0)91 524411
helena.lydon@universityofgalway.ie

Sponsor type
University/education

Website
https://www.universityofgalway.ie

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during the study will be available upon request from Helena Lydon (Helena.lydon@universityofgalway.ie). The data will be available following the publication of the research.

IPD sharing plan summary
Available on request