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Evaluation of a website for parents of children with juvenile idiopathic arthritis

Submission date
05/11/2015

Recruitment status
No longer recruiting

Registration date
05/11/2015

Overall study status
Completed

Last Edited
25/03/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Arthritis is a common condition which causes pain, stiffness and swelling (inflammation) in the joints. Arthritis is usually associated with older people, but it can also affect children. Most cases of arthritis in children are known as juvenile idiopathic arthritis (JIA), because the cause is not known (idiopathic). In order to be diagnosed with JIA, one or more joints must be inflamed for more than 6 weeks, in a child under the age of 16. The condition can cause considerable pain and distress to the child however it also has a significant impact on their family. It can be incredibly stressful for parents having to be faced with their child's pain and physical difficulties. The treatment of JIA is often complex, involving a number of different medications, hospital visits and physiotherapy, and some parents find it difficult to manage all of these aspects. There is a great deal of information available on the internet which can help parents to understand more about JIA. There is however a lack of resources which help parents to deal with the daily issues that they and their children could face. "WebParC" is a specially designed website which aims to help teach parents ways to cope, lowing their stress levels and improving their child's wellbeing. The aim of this study is to find out whether using this web-based tool can help to lower stress levels in parents who have children suffering from JIA.

Who can participate?
Adults who have a child that has been diagnosed with JIA within the last six months.

What does the study involve?
Parents are randomly allocated to one of two groups. Those in the first group are given access to WebParC for the 12 months of the study. Their child also receives their normal medical care throughout this time. Parents in the second group are not given any access to WebParC however their child continues to receive their normal medical care. At the start of the study, and then again after 4 and 12 months, parents are asked to complete a number of questionnaires designed to measure their stress levels, how well they are coping with their child's illness and how well they fell that their child is coping. Those that have access to the website will also complete questions regarding website usage.

What are the possible benefits and risks of participating?
If the website is effective, participants may benefit from enhanced parental ability to manage their child's JIA, which will reduce parental stress and improve their children's quality of life. There are no known risks of taking part in the study.

Where is the study run from?
Approximately 16 children's hospitals and clinics across England (UK)

When is the study starting and how long is it expected to run for?
July 2015 to September 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Sarrah Peerbux

Contact information

Type(s)
Public

Contact name
Miss Sarrah Peerbux

Contact details
School of Health Sciences
City University of London
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London
United Kingdom
EC1V 0HB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19872

Study information

Scientific Title
Assessment of a web-based tool for parents of children with Juvenile Idiopathic Arthritis (JIA) coupled with standard care versus standard care alone: A randomised controlled trial

Acronym
WebParC

Study objectives
The aim of this study is to investigate the benefits of having access to the WebParC in combination with standard care when compared to standard care alone. The study help to determine the value of making an authorised website available on a larger scale and encouraging parents to access it as part of managing their child’s condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bridge Research Ethics Committee, 14/10/2013, ref: 13/LO/0288

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Children, Musculoskeletal disorders; Subtopic: All Diagnoses, Musculoskeletal (all Subtopics); Disease: All Diseases, Studies involving Children and Adolescents

Interventions
Participants are randomly allocated to one of two groups:

Group 1: Participants are given access to a specifically designed website (WebParC) for parents of children with Juvenile Idiopathic Arthritis for a period of 12 months, in addition to their child's normal clinical care. WebParC has been systematically developed with healthcare professionals and parents of children with JIA to provide techniques for dealing with the daily issues in JIA.
Group 2: Participants continue with standard care alone for the 12 month study period and are not given access to the web-based tool.

At baseline, 4 and 12 months, participants complete a number of questionnaires to assess their stress levels, how their are coping and their child's wellbeing.

Intervention Type
Other

Primary outcome measure
Parental Stress is measured using the Paediatric Inventory for Parents (PIP) questionnaire at baseline, 4 and 12 months.

Secondary outcome measures
1. Parent effectiveness in managing their child's healthcare is assessed using the Effective Consumer Scale - Adapted (EC17-A) at baseline, 4 and 12 months
2. Parent self-efficacy in managing their child's arthritis is assessed using the Parent's Arthritis Self-Efficacy Scale (PASE) at baseline, 4 and 12 months
3. Parent coping is assessed using the Brief COPE at baseline, 4 and 12 months
4. Parent mood is assessed with the Hospital Anxiety and Depression Scale (HADS) at baseline, 4 and 12 months
5. Parent satisfaction with healthcare is assessed with the Client Evaluation of Service Questionnaire (CESQ) at baseline, 4 and 12 months
6. Child health-related quality of life is assessed with the parent administered version of the Child Health Questionnaire - PF50 (CHQ-PF50) at baseline, 4 and 12 months
7. Healthcare utilization is assessed by recording all contacts at the trial sites and with the Client Service Receipt Inventory (CSRI) questionnaire at baseline, 4 and 12 months
8. Dose-response relationship between the level of website usage and the primary and secondary outcomes, is determined by analysing website-based usage data at 12 months
9. Website usage is measured for the intervention group only at 4 and 12 months

Added 15/11/2016:
Process evaluation:
1. Illness beliefs in parents will be measured using the Brief Illness Perceptions Questionnaire (BIPQ) at baseline, 4 and 12 months
2. Acceptability will measured within a qualitative interview study using an topic guide based on an acceptability framework, on a small sample of parents from the intervention group (around 16 parents), randomly selected and invited to take part at 4 months
3. Website satisfaction and usage data will be assessed as part of the process evaluation by a satisfaction feedback questionnaire, administered to the intervention group at 4 and 12 months post randomisation
4. Context will be assessed by undertaking a survey assessing standard care across recruiting sites, and a survey of Clinical Nurse Specialists to give an overview of care packages delivered to patients and their families

Overall study start date
01/07/2015

Completion date
30/09/2019

Eligibility

Key inclusion criteria

1. Parents of children who have been newly diagnosed (within 6 months) with JIA according to internationally agreed criteria (Int. League against Rheumatism ILAR)
2. Aged 18 years or over
3. Ability to understand written and spoken English

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200; Description:
The standard deviation of scores on the EC-
17 is expected to be 17. Therefore, 79 households (118 parents) per groupwill be sufficient to dete

Total final enrolment
220

Key exclusion criteria
1. Identifiable psychosis or dementia in parents
2. Major problems with literacy making the completion of the questionnaires impossible
3. Too likely to be distressed by the study as judged by senior members of clinical staff

Date of first enrolment
01/01/2016

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital
Great Ormond Street

London
United Kingdom
WC1N 3JH

Study participating centre
Royal Manchester Children's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
New Cross Hospital
Royal Wolverhampton NHS Trust
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
University Hospital of North Staffordshire
Newcastle Road
Stoke on Trent
United Kingdom
ST4 6QG

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Alder Hey Children’s Hospital
E Prescot Rd
Liverpool
United Kingdom
L14 5AB

Study participating centre
Birmingham Children's Hospital NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
University Hospitals Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Great North Children's Hospital
Royal Victoria Infirmary
Victoria Wing
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Leeds Children's Hospital
Leeds Teaching Hospital
Clarendon Wing
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Study participating centre

Nuffield Orthopaedic Centre
Oxford University Hospitals
Windmill Road
Headington
Oxford
United Kingdom
OX3 7HE

Study participating centre
Southampton Children’s Hospital
119 Tremona Road
Southampton
United Kingdom
SO16 6HU

Study participating centre
Addenbrooke's Hosptial
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Robert Jones and Agnes Hunt Orthopaedic Hospital
Gobowen
Oswestry
United Kingdom
SY10 7AG

Study participating centre
Shrewsbury and Telford Hospital
Evolution Road
Shrewsbury
United Kingdom
SY3 8XQ

Sponsor information

Organisation

City University London

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Sponsor type
University/education

ROR
https://ror.org/04489at23

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of a study protocol paper in June 2016 and results data in January 2020.

Intention to publish date
31/01/2020

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at EULAR	01/06/2020	14/09/2020	No	No
Results article		12/05/2022	16/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article	Economic evaluation of a trial exploring the effects of a web-based support tool for parents of children with juvenile idiopathic arthritis	22/03/2024	25/03/2024	Yes	No