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MyHealthE (MHE): Improving the collection of electronic outcome measurement in child and adolescent mental health services

Submission date
25/03/2019

Recruitment status
No longer recruiting

Registration date
29/07/2019

Overall study status
Completed

Last Edited
30/09/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Patient-reported outcomes (PROMs) are collected routinely by Child and Adolescent Mental Health Services (CAMHS) and provide essential information about the patient or main caregiver's perspective of treatment progress. National guidelines set out best practice recommendations for the type and frequency of PROM collection. At the moment most PROMS are collected within the clinic setting using paper-based questionnaires. However, across the UK CAMHS services tend to collect PROMs at much lower rates than clinical guideline recommendations, and there is a real need to improve on current paper-based approaches. Remote monitoring technologies could improve PROM collection rates in CAMHS. The aim of this study is to test whether an online tool (MHE: MyHealthE) will result in increases in completed PROM questionnaires over the course of CAMHS treatment. MHE was designed to provide caregivers with secure and engaging way to complete PROM information about their child on any internet enabled device. A secondary aim is to investigate the effect MHE introduction has on routine clinical practice, including whether the system is acceptable to caregivers, clinicians and what features can be changed, added or taken away to improve the system. The study will collect data from interviews conducted with caregivers and clinicians and economic questionnaires from clinicians to evaluate the feasibility and usability of the MHE system.

Who can participate?
Patients aged 4 -18 under the care of Lewisham NDT with a diagnosis of Autism Spectrum Disorder (ASD) and or Attention Deficit Hyperactivity Disorder (ADHD) and their caregivers.

What does the study involve?
Caregivers are randomly allocated to one of two groups. Caregivers allocated to the intervention group use the online tool to complete questionnaires for three months, and those allocated to the control group complete paper questionnaires in accordance with clinical discretion. Individual caregiver and clinician focus groups are conducted to assess the acceptability of the MHE system and targeted phone interviews are carried out with caregivers who failed to engage or disengaged with MHE. Potential economic benefits are assessed using clinician-reported questionnaires. Usual care continues for both groups.

What are the possible benefits and risks of participating?
The potential benefits include providing participants with a better way to report and track their child's symptoms, which could be used to measure and improve the effectiveness of CAMH Services as a whole. No major risks have been identified. Caregiver participation will not affect the level of care provided for their child and all information collected through MHE will be managed in the same way as all other confidential information is stored in their child's electronic health care records. Unforeseen application breakages could inconvenience participants but would not comprise patient information safety.

Where is the study run from?
Lewisham Neurodevelopment Team (UK)

When is the study starting and how long is it expected to run for?
November 2016 to May 2019

Who is funding the study?
Guy's and St Thomas' Charity (UK)

Who is the main contact?
Dr Johnny Downs
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SLaM QI/ Service approval panel ref: 07/04/17

Study information

Scientific Title
Enhancing the collection of electronic outcome measurement in child and adolescent mental health services: MyHealthE (MHE), a randomised controlled pilot study

Acronym
MyHealthE (MHE)

Study objectives
1. Introducing MHE will achieve a large increase in the amount of standardised caregiver-reported follow-up data, as measured by a count of how many SDQ forms have been filled across the control and intervention group.
2. Introducing MHE will improve caregiver satisfaction with services and clinician satisfaction with administrative workload, as assessed by individual phone and face-to-face consultations and separate caregiver and clinician focus groups.
3. Introducing MHE will reduced cost of SDQ delivery, evaluated using cost data per every SDQ completed to assess the difference in spend on the current resources dedicated to follow up SDQ data collection compared to the costs of providing MHE.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2017, South London and Maudsley NHS Foundation Trust Quality Improvement and Service Evaluation Ethics panel, Contact: Charlotte Laxton (CAMHS Business Planning Manager, South London and Maudsley NHS Foundation (SLAM) Trust, Michael Rutter Centre, De Crespigny Park, London, SE5 8AZ; Tel: +44 (0)203228 2693, +44 (0)7525236905)

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not currently available online, please request a patient information sheet from the primary contact

Health condition(s) or problem(s) studied
Neurodevelopmental disorders and co-morbid mental health disorders

Interventions
This randomised controlled pilot trial will include active patients who are under the care of the South London and Maudsley Hospital Lewisham Neurodevelopmental Team (NDT) and their caregivers. Caregivers are randomised by sequential randomisation. Caregivers randomised to the intervention will use the online tool for three months to complete SDQ, those randomised to control will complete paper-based SDQ in accordance with clinical discretion. Individual caregiver and clinician focus groups will be conducted to assess acceptability of the MHE system and targeted phone interviews will be carried out with caregivers who failed to engage or disengaged with MHE. Potential economic benefits will be assessed using clinician reported questionnaires. Usual care will persist for all participants irrespective of condition assignment.

To collect clinically relevant information, MHE automatically extracts caregiver mobile numbers and or email addresses held within hospital electronic health records to send out text messages and emails to caregivers and invite them to register on a personalised web-portal. After registration, MHE prompts caregivers to complete an SDQ form, and then at monthly intervals or weekly intervals until each requested from is filled. Their responses are automatically scored by the application and the results are displayed within their personalised portal in the form of basic graphs and visualisations and incorporated into their electronic health records (initially manual entry, and then via automated entry) making them available to their treating clinician.

Intervention Type
Other

Primary outcome measure
Follow-up SDQ completion at 3 months from enrolment, as measured by a count of how many SDQ forms have been filled in across the control and intervention groups at baseline and 3 months

Secondary outcome measures
1. Acceptability measured by focus groups and individual (phone and face-to-face interviews) at 3 months
2. Economic benefit measured by clinician reported SDQ administration cost questionnaire, including estimated time spent administer, following-up completion and scoring SDQ in the last week to be collected at monthly intervals
3. Drop-out due to internet access measured by reasons given for participant drop out as measured by targeted caregiver face-to-face and phone interviews at 3 months

Overall study start date
21/11/2016

Completion date
11/05/2019

Eligibility

Key inclusion criteria
1. Patients aged between 4 -18 years old with under the care of Lewisham NDT with a diagnosis of Autism Spectrum Disorder (ASD) and or Attention Deficit Hyperactivity Disorder (ADHD)
2. Have at least one SDQ present in their electronic health records

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
A threshold of clinical significance was decided a priori to be 15% between TAU and the intervention group. A previous audit provided an expected baseline of 8% SDQ completion in the control group. For a fixed sample size design, the sample size required to achieve a power of 1-β = 0.80 for the one-sided chi-square test at level α = 0.05, under the prior assumptions and clinical significant criteria was 2 × 90 = 180. The power calculation was carried out using Gpower 3.1.7.

Key exclusion criteria
1. No baseline SDQ present in their electronic health records
2. Caregiver contact information not present in the patient's electronic health records
3. Patients and their caregivers no longer active cases within SLaM Child and Adolescent Mental Health Services
4. Caregiver does not have access to a mobile internet enabled device

Date of first enrolment
11/02/2019

Date of final enrolment
11/02/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lewisham Neurodevelopment Team
Lewisham Neurodevelopment Team
Kaleidoscope
32 Rushey Green
Catford
Greater London
United Kingdom
SE6 4JF

Sponsor information

Organisation
Guy’s and St Thomas’ Charity Health Innovation Fund

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Guy's and St Thomas' Charity
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Sponsor type
Charity

Website
https://www.gsttcharity.org.uk/

ROR
https://ror.org/02p7svq74

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity

Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings from this study will help understand whether MHE should be extended across other SLAM CAMH services. The findings will also be presented in high-impact peer-reviewed medical journals and at meetings and conferences with other health care professionals.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
Caregiver-reported SDQ data is being collected as part of routine clinical care and will be stored in the patient's electronic health records and a secure cloud-based database held within the Trust's firewall. Qualitative data from caregiver and clinical interviews will be transcribed and stored securely on Trust terminals. Economic data collected using paper-based questionnaires will also be converted to an electronic format and held on SLaM terminals. Transcripts and raw economic data will be available upon request where appropriate.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/06/2022	30/09/2022	Yes	No