

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

<b>Submission date</b> 25/03/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/09/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 compromise 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

johnny.downs@kcl.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Johnny Downs

**ORCID ID**

<http://orcid.org/0000-0002-8061-295X>

**Contact details**

Department of Child and Adolescent Psychiatry – PO85

Institute of Psychiatry, Psychology and Neuroscience

16 De Crespigny Park

Greater London

United Kingdom

SE5 8AF

+44 (0)7951273511

johnny.downs@kcl.ac.uk

## 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 form 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  $1-\beta = 0.80$  for the one-sided chi-square test at level  $\alpha = 0.05$ , under the prior assumptions and clinical significant criteria was  $2 \times 90 = 180$ . 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

**Sponsor details**  
Guy's and St Thomas' Charity  
Francis House  
9 King's Head Yard  
London  
United Kingdom  
SE1 1NA  
+44 (0)20 7089 4550  
info@gsttcharity.org.uk

**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?
<a href="#">Results article</a>		09/06/2022	30/09/2022	Yes	No