

TIA: a feasibility study of telemedicine in addictions

Submission date 14/11/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/12/2019	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 07/06/2023	Condition category 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

Opioids are very strong painkillers that are good for acute pain and pain at the end of life but there is little evidence that they are helpful for long-term pain. Despite this, they are widely prescribed for this reason in the UK. When opioids are used for long periods of time, they cause changes in the body which mean that to stop taking them is a very unpleasant mental and physical experience – this is known as dependence.

Opioid dependence is a chronic condition with high risks. Opioid substitution treatment with methadone or buprenorphine helps to improve outcomes. Department of Health UK guidelines recommended service users prescribed opioid substitution treatment have an addictions prescriber appointment every twelve weeks. This is to help improve health, wellbeing, recovery needs and ensure medication safety.

We have found that some service users do not attend appointments. This study will see if using telemedicine for appointments helps service users attend appointments.

Telemedicine is the use of Skype video calling. Service users would see their prescriber through their healthcare workers laptop. The prescriber would be at another location. This may help reduce travel, as service users could attend an appointment near to their home

Who can participate?

Service users with opioid dependence, prescribed opioid substitution treatment, and attending an outreach clinic are eligible for the study

What does the study involve?

Service users who accept to participate in the study will be randomly assigned to either telemedicine appointments or face-to-face appointments (treatment as usual). Service users will have their next two addiction prescriber appointments as either telemedicine appointments or face-to-face appointments.

Information will be collected on attendance rates, patient satisfaction and travel distance for service users, and also from staff on their experience of Telemedicine and the trial. Information from this smaller study will be used to inform a future larger study to help develop better access to addictions treatment

What are the possible benefits and risks of participating?

Benefits to trial participants may be that this intervention helps a participant attend appointments. This would also help the knowledge base on telemedicine in addictions.

Risks: none anticipated

Where is the study run from?

East Riding Partnership - Humber NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?

September 2019 to May 2020

Who is funding the study?

1. East Riding Clinical Commissioning Group, UK
2. Academic Health Science Network, UK

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

259335

Protocol serial number

V1130619

Study information

Scientific Title

Telemedicine in Addictions Randomised Controlled Trial

Acronym

TIA

Study objectives

Telemedicine consultations may improve attendance at addiction prescriber appointments

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/08/2019, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (St Luke's Hospital, Extension Block, Little Horton Lane, Bradford, BD5 0NA, UK; +44 (0)207 104 8018; nrescommittee.yorkandhumber-bradfordleeds@nhs.net) ref: 19/YH/0237, IRAS project ID: 259335

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Opioid dependence

Interventions

Service users who accept to participate in the study will be randomly assigned to either Telemedicine appointments or face-to-face appointments (treatment as usual). Service users will have their next two addiction prescriber appointments as either Telemedicine appointments or face-to-face appointments.

Information will be collected on attendance rates, patient satisfaction and travel distance for service users, and also from staff on their experience of Telemedicine and the trial. Information from this smaller study will be used to inform a future larger study to help develop better access to addictions treatment.

The first consultation will be offered within 4 weeks of consent, the second consultation will be within 12 weeks of the first consultation, follow up interviews within 4 weeks of the second consultation. The patients will be within the study for 20 weeks.

Randomisation will be carried out after consent has been gained and the initial baseline assessment has been conducted. This will be conducted via Red Cap Cloud to randomize 60 participants into two treatment groups with 1:1 ratio, using random permuted blocks. A remote randomisation procedure will be used through Red Cap data management to generate the treatment allocation, which will be initiated by a trained researcher. It is not possible for participants and the study team to be blind to treatment allocation due to the treatment intervention.

Intervention Type

Behavioural

Primary outcome(s)

Attendance at appointments measured using electronic care records

Feasibility outcomes:

1. Recruitment rate measured using a count of consent forms at follow-up (20 weeks)
2. Retention rate measured using a count of completed questionnaires at follow-up (20 weeks)
3. Acceptability of the study - views and experiences of service users and staff measured using a research interview at follow-up (20 weeks)

Key secondary outcome(s)

1. Patient satisfaction measured using the Patient Satisfaction Questionnaire (PSQ) and the Telemedicine Satisfaction Questionnaire (TSQ) (Telemedicine arm only) at the end of the first and second consultations
2. Travel distance measured using electronic care records
3. Addiction changes that occur during treatment measured using the Treatment Outcome Profile (TOP) and urine tests at baseline and at follow-up (20 weeks)
4. Patient and staff evaluation of the process measured using a process evaluation interview at follow-up (20 weeks)
5. Addictions prescriber satisfaction measured using a non-validated questionnaire at follow-up (20 weeks)

Completion date

10/06/2020

Eligibility

Key inclusion criteria

1. Diagnosis of opioid dependence
2. Prescribed opioid substitution treatment (OST) e.g. methadone or buprenorphine
3. Aged 18 years to 65 years
4. Willing and able to provide informed consent
5. Attending an outreach (spoke) clinic for keyworker appointments

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Service users who cannot read English AND would require the service of an interpreter to understand a brief oral description of the study
2. Service users who have already entered the trial

Date of first enrolment

24/09/2019

Date of final enrolment

28/02/2020

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

East Riding Partnership - Humber Teaching NHS Foundation Trust

7 Baker Street

Hull

United Kingdom

HU2 8HP

Sponsor information**Organisation**

Humber Teaching NHS Foundation Trust

ROR

<https://ror.org/016bnqk64>

Funder(s)

Funder type

Government

Funder Name

East Riding Clinical Commissioning Group

Funder Name

Academic Health Science Network

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. Hull Health Trials Unit, University of Hull, using two cloud based systems – REDCap Cloud and Box.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Participant and staff satisfaction results presented at the Royal College of Psychiatrists Virtual International Congress	18/06/2021	06/09/2021	No	No
Abstract results	Participant experience data presented at the Royal College of Psychiatrists Virtual International Congress	18/06/2021	06/09/2021	No	No
HRA research summary			28/06/2023	No	No
Other publications	Title: Patient Satisfaction with Telemedicine in Addictions	01/08/2021	06/12/2021	Yes	No
Protocol file		13/06/2019	05/12/2019	No	No