

Feeling Well with True Colours for community patients

Submission date 08/08/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/08/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/08/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The management of mental illness involves collaboration between the patient and the health care professional. A key part of this collaboration is patients monitoring of their symptoms and problems themselves. However, it is widely acknowledged that regular monitoring of symptoms is difficult to maintain, and yet these are typically lifelong conditions. We need a straightforward, user-friendly technology that allows patients to self-monitor relatively effortlessly, and enables the resulting data to be shared by the patient with their key clinicians. True Colours has been developed to facilitate such self-monitoring in common mental illnesses, including bipolar disorder, schizophrenia, depression and anxiety, and common associated problems, including alcohol and substance misuse. It is, therefore, potentially a useful clinical tool for use by Community Mental Health Teams (CMHTs) and their patients in the UK. We need to find out whether this service, Feeling Well with True Colours, works and is cost effective when adopted by UK CMHTs.

Who can participate?

All 11 CMHTs in Oxford Health NHS Foundation Trust, UK will take part in this study.

What does the study involve?

The order in which the participating CMHTs introduce True Colours will be randomly decided ('by the flip of a coin'). All 11 CMHTs will introduce the service, and we will compare the information gathered by each CMHT before and after the start of the service.

What are the possible benefits and risks of participating?

Patients may benefit from managing their mental illness better if this is adopted by the CMHTs. There are no anticipated risks for participants or CMHTs.

Where is the study run from?

The study is run from Oxford Health NHS Foundation Trust covering Oxfordshire and Buckinghamshire, UK.

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

Training for CMHTs begins in June 2013 and will be completed by the end of December 2013.

Who is funding the study?
The National Institute for Health Research (NIHR), UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14330

Study information

Scientific Title
Stepped wedge cluster randomised controlled trial of Feeling Well with True Colours for community patients in Oxford Health NHS Foundation Trust: quantitative evaluation

Acronym
OXTEXT-7: Quantitative evaluation

Study objectives
Feeling Well With True Colours (FWWTC) is a series of 6 booklets that have been designed to be used with the True Colours self-monitoring and management system. The booklets cover a wider

range of mental health disorders, including, bipolar disorder, unipolar depression, anxiety, schizophrenia and psychosis, alcohol and substance misuse and managing medicines. Likewise the True Colours electronic monitoring system has been expanded to include new questionnaires for monitoring the above conditions. Previously True Colours has only been used with bipolar disorder. This study will evaluate whether:

1. Feeling Well with True Colours is as effective with other mental health disorders as it is with bipolar disorder.
2. Whether Feeling Well with True Colours improves health outcomes, and is cost-effective, when rolled out across all of the Adult Community Mental Health Teams (CMHTs) in Oxford Health NHS Foundation Trust.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/SC/0070; First MREC approval date 15/03/2013

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please contact oxtext@psych.ox.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Service Delivery; Disease: Not Applicable

Interventions

Feeling Well with True Colours, will be offered to every patient in a CMHT who the clinician (doctor, nurse, psychologist, other therapist) feels would benefit from developing self-monitoring and self-management skills. The intervention comprises two elements:

1. self-monitoring of symptoms via the True Colours system
2. patient education about self-monitoring, via Feeling Well materials

Follow Up Length: 15 month(s); Study Entry : Single Randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Health of the Nation Outcome Scales (HoNOS) Score; Timepoint(s): monthly

Secondary outcome measures

1. Change in DH Mental Health Clusters (derived from HoNOS) at CMHT level every month.
2. Number of face-to-face-contacts V non face-to-face contacts collected monthly for each CMHT.
3. Length of stay on CMHT caseload collected monthly for each CMHT.
4. Number of hospital admissions/discharges/length of stay on wards collected monthly and mapped to CMHTs.
5. Number of emergency re-admissions for each ward collected monthly and mapped to CMHTs.
6. Number of admissions under Mental Health Act Section for each ward collected monthly and mapped to CMHTs.
7. Missed appointments by staff collected monthly for each CMHT.
8. Missed appointments by patients collected monthly for each CMHT.
9. Appointments cancelled by staff collected monthly for each CMHT.
10. Appointments cancelled by patients or staff collected monthly for each CMHT.
11. Staff performance measures collected monthly for each CMHT, including:
 - 11.1. Sickness levels
 - 11.2. Unfilled vacancy levels
 - 11.3. Staff turnover
 - 11.4. Staff stability
 - 11.5. Staff costs

Overall study start date

01/06/2013

Completion date

31/01/2014

Eligibility

Key inclusion criteria

The unit of randomisation for this trial will be 11 adult Community Mental Health Team (CMHT) of Oxford Health NHS Foundation Trust covering the two counties of Oxfordshire and Buckinghamshire. Strictly, the study participants are, therefore, clinical teams, rather than patients. CMHTs will be included if they are:

An Adults of Working Age Community Mental Health Team(CMHT) located in Oxfordshire or Buckinghamshire (and therefore part of Oxford Health NHS Foundation Trust).

Clinicians working within the CMHTs will decide to which patients it is appropriate to offer FWwTC. It is likely that these patients will:

1. Have any psychiatric disorder or disorders
2. Be able, in the view of the managing clinician, to benefit from self-monitoring and management
3. Be able to weigh the pros and cons of using FWwTC, and make a decision on what they want to do

4. Be able to use SMS (text messaging) or email/internet

5. Have reasonable written and spoken English.

Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 500; UK Sample Size: 500; Description: 11 adult CMHTs. Study team advised sample size will be between 500-2000 participants 1/7/13.

Key exclusion criteria

Only those implied by the inclusion criteria.

Date of first enrolment

01/06/2013

Date of final enrolment

31/01/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Psychiatry

Oxford

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Sponsor information

Organisation

University of Oxford (UK)

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Sponsor type

University/education

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

NIHR Programme Grants for Applied Research, UK. Grant Codes: RP-PG-0108-10087

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No