East London NHS Foundation Trust

STUDY PROTOCOL

Mobile technology health solutions for patients with severe mental illness – A feasibility RCT

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1. Background:

Severe mental illness (SMI), in particular chronic psychosis (Schizophrenia, Schizoaffective Disorder, Bipolar Disorder), is highly prevalent and associated with significant costs to the NHS accounting for appr. 12% of the total budget. Current routine appointment systems do not systematically capture information suggestive of urgent care needs. The complexity of the disorder patients require multidisciplinary flexible care arrangements involving different providers, often resulting in poor treatment adherence and problems with therapeutic engagement. Consequently, a significant number of patients suffer with social isolation and poor quality of life.

Therapeutic engagement and adherence to treatment (medication / other aspects of psychosocial care) are important predictors of illness course and outcome in SMI. Non-adherence to prescribed antipsychotic medication is a common phenomenon (25-55%, e.g. Kane et al. 2013), associated with symptomatic relapse (e.g. Fialko et al 2008).

There is a paucity of research investigating the effects of interventions to improve therapeutic engagement and compliance. Puschner et al. (2005) conducted a review and found that psychoeducation had limited effect and CBT combined with other interventions at its best had a moderate effect. McCabe et al. (2013) investigated psychiatrist-patient communication and found that effective communication, including a shared understanding, is associated with better treatment adherence. Often patients do not timely communicate issues of non-compliance due to side-effects or other concerns to their health professionals, partially because the time between routine medical appointments can be rather long (e.g. Goff et al. 2010).

New and cost-effective ways of delivering integrated health / social care for patients with SMI are required. This pilot study is aiming to explore the clinical benefits of an enhanced community care intervention that uses an interactive simple technology based (SMS text messaging) communication system. This system – called 'Florence' – is providing a user friendly, easy to use and non-stigmatising add-on to the current care pathway at low cost. Service users can use the system free of charge on their own mobile phones. The intervention is provided in the spirit of recovery oriented care and supports service users gaining more control over their problem monitoring as well as the necessary appointment arrangements with health professionals.

Four previous non-controlled pilot trials addressed the question of the usefulness of mobile health technologies (M-health according to Hollis et al. 2015) for symptom monitoring in patients with SMI and reported a reduction of hospitalizations, improvement in self-reported symptoms and illness self-management skills (Spaniel et al. 2008, Granholm et al. 2012, Godleski et al. 2013, Pratt et al. 2014). But no RCT to date addressed their usefulness for interactive engagement of patients with SMI (chronic psychosis) in comparison with community treatment as usual.

One previous (non-controlled) open trial (Spaniel et al. 2008) assessed the effects of weekly monitoring of early warning signs of schizophrenia via text messaging, but professionals determined the clinical threshold for urgent interventions.

The 'Florence Simple Telehealth system' is an interactive M-health technology (see classification outlined by Hollis et al. 2015) that is easy to use on patient's own mobile phones free of charge. It allows for information monitoring by clinicians through an online server and for disorder specific and individually tailored direct communication between service users and health care professionals. This includes using reminders / prompts and abbreviated information sharing, allowing for symptom and compliance monitoring as well as alert-triggered interventions.

So far there is only evidence available regarding its effectiveness for patients with medical conditions including Hypertension, Asthma & COPD, and smoking cessation from a large cohort (N=3381) service evaluation.

Apart from promising single case studies and one small cohort study for patients with generic (mild to moderate) mental health problems 'Florence' has not yet been used in the treatment or management of patients with severe mental illness.

A literature review (e.g. Hollis et. al. 2015) indicated that to date no randomised controlled trial evaluating the usefulness (clinical effectiveness) of mobile health technologies for patients with severe mental health problems has been conducted.

There is therefore currently insufficient evidence to recommend increased uptake of the intervention to commissioners and providers.

This study is aiming to contribute to the evidence gap in respect of M-health technologies for the treatment of SMI conditions. Consulting with international experts from WHO Collaboration Centre for Mental Health Service (Newham) we established that whilst technology-based symptom monitoring appears to be an accepted complement to clinical practice, participants' experiences have rarely been explored in-depth (Walsh, Giacco & Priebe, in press) which this study is going to address.

The intervention combines innovatively the potential benefits of the Florence technology for patient's treatment adherence / therapeutic engagement with a system that allows to direct clinician's attention to actual clinical needs in a timely fashion. Patient's wellbeing scores and individually agreed simple text messaging codes are utilised to foster patient-clinician communication outside routine appointments. The subjectively derived number scores act as trigger points (threshold indicators) for follow-up meetings.

Cottrell et al. (2015) emphasised the need for enhanced support in order to improve longer-term service uptake of mobile technology. The researchers in this study will not only collect data but also help patients and clinicians to make best use of the interactive technology.

2. Major aim of the project:

This study is aiming to contribute to the evidence gap in respect of M-health technologies for the treatment of SMI conditions. The feasibility pilot RCT aims to explore an innovative approach that not only uses the telehealth technology as a monitoring tool but also as a structured engagement tool to complement and inform direct clinical meetings between patients and staff.

In addition, the intervention is going to test the usefulness of non-elicited messaging options for patients who opted in to participate to signal areas of needs and subjectively (individually) derived risk scores as threshold indicators for direct follow-up meetings between patient and HCP.

Aim

The project will test the feasibility and evaluate the effectiveness (six months after baseline) of a mobile technology intervention in comparison with routine care (intervention additional to treatment as usual) for patients with severe mental illness, aiming to foster self-management and timely communication between patients and clinicians, hereby impacting upon treatment adherence and relapse rates.

Evaluating potential impacts of the intervention on clinical outcomes: Increase of frequency and clinical utility of patient-clinician contacts, their impact on better compliance with medication and other aspects of treatment regime (resulting in reduced relapse rates and increased service user satisfaction / self-management skills).

Objectives

- To improve patient's self-management skills (self-efficacy and self-confidence)
- To increase the frequency and to hereby enhance the clinical utility of patient-clinician interaction
- To support patients to achieve better compliance with medication and other aspects of the treatment regime (impacting upon relapse rates through timely responses to crisis).
- To introduce real time monitoring of patient reported outcome measures (PROMs) / wellbeing and relapse indicators.

Specific (exploratory) research questions:

The exploratory trial will test the feasibility and collect data regarding the clinical usefulness of technology assisted enhanced mental health care in the community.

1. Is it feasible to implement the telehealth technology ("Florence") for routine care processes in community mental health services in terms of practicalities and patient as well as health professional engagement?

2. Do patients, who have been identified as potentially benefiting from the enhanced care component, engage in a meaningful way with the interventions offered to them?

3. To what extent might patients who participate in the intervention benefit in terms of improvements in their treatment adherence with corresponding relapse rates, their self-management capabilities and their satisfaction with treatment as well as their subjective quality of life (as compared with a similar group of patients who receive treatment as usual)?

4. Are the findings suggestive of potential cost benefits of the additional intervention?

Methods:

DESIGN: Exploratory randomised controlled feasibility trial. A sample of 60 (to 80) service users with SMI receiving mental health care in Newham / London will be recruited from community mental health teams (CMHTs). Patients will be randomly assigned to treatment as usual (TAU) or to the intervention in addition to TAU.

SETTING: Secondary Care community mental services in East-London

IDENTIFICATION OF POTENTIALLY SUITABLE PATIENTS:

RECRUITMENT:
active identification through data-base and subsequent referral from primary health services;
potentially suitable patients will be contacted by a member of the clinical care team and referred for study participation once verbal consent was obtained by clinicians.

PATIENTS:

INCLUSION CRITERIA:
All patients who receive currently mental health care from one of the community mental health teams provided by East London NHS Foundation Trust and who have an established diagnosis of Severe Mental Illness (Schizophrenia, Schizoaffective Disorder, Bipolar Disorder); patients will be 18-65 years old and have an appointed mental health professional. A basic command of English is required to understand the nature, purpose, requirements and procedures of the study participation.

EXCLUSION CRITERIA:
Patients who lack capacity (as assessed pre consent giving by patient's clinicians), Organic psychosis, Learning Disability, no basic command of English, currently inpatient.

THE INTERVENTION:

TAU involves routine follow up as per existing care provisions with regular face-to-face care-coordinator contacts and 3-6 monthly medical reviews with a psychiatrist.

The intervention consists of enhanced community follow up for SMI patients, utilising the M-health 'Florence' Simple Telehealth system. The system is already available within the organisation (Community Health Newham) for long-term condition physical health care to improve treatment adherence and patient engagement/self-management (with direct benefit). Based upon those successfully implemented principles, the team developed a mental health specific version of Florence text messaging interventions.

Patients will be introduced to 'Florence' at a face-to-face meeting with the researcher and care co-ordinator and will receive an instruction leaflet. (Previous experience suggests that patients prefer to use their own mobile phone as they are familiar with its functions). Participating patients who do not have a phone or who prefer to use one specifically only for the intervention will be provided with a mobile phone.

'Florence' sends patients four SMS text messages daily: two reminders for medication adherence or appointments and two asking patients to send their wellbeing and relapse indicators. These latter messages are patient specific, based on individually identified relapse indicators (e.g. sleep, anxiety, voice-hearing intensity – see appendix). The messages prompt patients to contact their care co-ordinator to discuss problems arising. Also, at any time patients can use 'Florence' to send a message requesting support using a predefined lists of codes (see appendix). In response the care coordinator will contact patients to get more detailed information regarding the nature of the problem arising and with a view to agree on appropriate actions to take.

Patients will be contacted by phone by the care coordinator if not sending daily messages with wellbeing/relapse indicator score for 7 consecutive days. Both the researcher and care coordinator have direct access to the message monitoring system online; if a patient texts back a relapse indicator score of >=5 the care coordinator will arrange for a telephone/Skype or face to face contact within 24 hours weekdays or at the first day of the week if the message was sent on weekend days.

OUTCOME MEASURES
(baseline compared with post−intervention at 6−month follow−up):

Measurement plan:

A. Baseline characteristics: sociodemographics; diagnosis/ICD code, care cluster, medication prescribed, number of previous hospitalisations, last hospitalisation, duration of illness, history of relapse due to non-compliance (rated by clinician on 5-point scale: "yes, known", "likely, but not known", "no, not known")
B. Collecting data regarding SMS text messaging response rates as well as patient text inputs into the system (recorded directly from the telehealth system).

C. Clinical outcomes (Baseline & follow-up assessment after six months): treatment adherence (compliance with medication, attendance at therapeutic / clinical appointments: Medication Adherence Rate Scale / MARS, SMS response rates and attendance rates) and relapse rates (number of hospital admission, number of Crisis Resolution Team inputs, number of A&E attendances)
D. Other outcomes (Baseline & follow-up assessment after six months): Service user satisfaction with treatment (Client's Assessment of Treatment Scale and DIALOG scale), subjective QoL (Manchester Short Assessment of Quality of Life scale), factors contributing to effective self-management skills (General Self Efficacy Scale and Mental Health Confidence Scale) and information regarding experiences using m-health technology intervention and acceptance of Florence system (semi-structured interview at follow-up with service users and clinicians).

STUDY PHASES:

Two representative consultation groups with service users and staff, presenting the study design, adapting the intervention as required. Preparing all required materials and data entry system. Setting up Florence system (adopted from existing service), recruitment of research assistants.

Month 1-3 (preparation phase):
Setting up infrastructure (including Florence technology system) for study conduct. Prepare identification of suitable patients for recruitment and assessment according to inclusion criteria: all community patients (age 18-65) from CMHTs in Newham with a diagnosis of SMI (Schizophrenia, Schizoaffective Disorder, Bipolar Disorder) have a care coordinator (basic command of English required).

These patients will be approached consecutively by clinicians, given a participant information sheet and asked to participate in the study, until the target number of 30 patients in each cohort has been recruited. Once confirmed the researcher will arrange for a meeting for written informed consent, baseline assessments and technical instructions for mobile technology.
Patients who do not owe a mobile phone will be provided with a phone for the study.
Patients will be randomly allocated to the intervention or control (TAU) condition based upon computer-generated numbers (processed and assigned independently by staff from the academic unit, not involved with the study project otherwise).

Months 4-8:
Recruitment and baseline assessments. The clinical teams follow up patients according to the clinical protocol for Florence triggered care arrangements. On-going data entry and presentation.

Months 9-14:
Conducting 6-months follow-up assessments according to protocol including obtaining narratives from participants and staff (semi-structured interview).
The clinical teams continue to follow up patients according to the protocol.

Months 13-15:
Obtain missing data from clinical record systems and through face-to-face contacts with patients and staff, data analysis, data presentation, preparing manuscripts for publication, attending public events and conferences for presentation of findings.

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Appendix:

Relapse indicator matrix (only as guidance for patient daily monitoring)

Individual marker, e.g. / Intensity scores	No problem	Moderate problem	Severe problem	Scoring
Sleep	0	1	2	0-2
Anxiety	0	1	2	0-2
Voices	0	1	2	0-2

Total of 0-6

Intensity of problem relapse indicator:

0	1	2	3	4	5	6
No problems	Only Minor problems	Only Some problems	In the middle	More Problems	Severe problems	Crisis problems

Predefined list of codes requesting support from care coordinator:

1=mental health
2=physical health
3=safety
4=medication
5=side effects
6=relationships
7=finance
8=housing