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Text messages to support the well being of patients with severe mental health problems

Submission date	Recruitment status	[X] Prospectively registered
12/05/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/07/2017	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
132581

Study information

Scientific Title
Mobile telephone text messages to encourage compliance with medication and to follow up with people with psychosis: a multi-centre randomised controlled two-armed trial

Acronym
Mobile.Net

Study objectives
SMS use will reduce service use of people with serious mental illness whose use of services has been high.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of The Hospital District of Southwest Finland, 16/12/2010, ref: 109/180/2010

Study design
Multi-centre randomised controlled two-armed trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet (in Finnish)

Health condition(s) or problem(s) studied
Psychosis

Interventions
Intervention group will receive the SMS messages (a semi-automatic system) at out-patient care after their discharge from acute psychiatric in-patient care. The SMS messages to the patients will continue for the end of the study period or until they wish these messages to stop. The intervention will be consumer-led rather than researcher-led to increase acceptability of the prompt. Therefore, the format and frequency of the messages to be sent will be all agreed with the patient. For example, patients choose text messages content areas related to their medication and/or keeping appointments. Additionally, they can choose messages related to other daily issues (e.g. taking care of hygiene, physical exercise, nutrition, day routines, wearing,

avoiding danger, communication, taking care of pets, following rules, hobbies, work or other activities, house hold, symptom management or other supporting messages). The content of the messages mentioned have been designed by patients in rehabilitative units in Finland. Patients /their career can inform the Data Manager who can change the system based on patients' wishes. In addition, patients in intervention group receive standard care with face-to-face sessions with staff.

Patients in control group ('treatment as usual') receive standard care.

Total duration of treatment: 12 months, total duration of follow-up: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Admission to psychiatric hospital (register data). Data collection will take 12 months follow-up from baseline

Secondary outcome measures
1. Use of social and health care services. Data collection will take 12 months follow-up from baseline:
1.1. Involuntary treatment in psychiatric hospital (register data)
1.2. Use of coercive measures (register data)
1.3. Use of specialiced mental health in- and out-patient care (register data)
1.4. Use of primary health care, health care centers (register data)
1.5. Use of reimbursements of National Health Insurance (register data)
2. Adverse events (register data). Data collection will take 12 months follow-up from baseline
3. Patient requests to stop the text-messages. Data collection will take 12 months follow-up from baseline
4. Drop-outs, data collection will take 12 months follow-up from baseline
5. Quality of life (Q-Les-Q, Endicott ym. 1993, 14 questions). Data collection will take 12 months follow-up at two points: at baseline and at 12 months
6. Satisfaction with treatment Client Satisfaction Questionnaire (CSQ-8). Data collection will take 12 months follow-up at two points: at baseline and at 12 months

Overall study start date
01/06/2011

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Aged 18 - 65 years, either sex
2. Antipsychotic medication
3. Discharged from psychiatric hospital
4. Have mobile phone

5. Able to use Finnish language
6. Able to give written informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3100, 1550 for both arms

Key exclusion criteria
1. Unable to use the Finnish language
2. Unable to give written informed consent to participate
3. Planned non-acute treatment period or visit in-psychiatric hospital
4. Forensic patients

Date of first enrolment
05/09/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Finland

Study participating centre
University of Turku
Turku
Finland
20014

Sponsor information

Organisation
Academy of Finland (Finland)

Sponsor details
Vilhonvuorenkatu 6
PL 99
Helsinki
Finland
00501
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Sponsor type
University/education

Website
http://www.aka.fi/en-GB/A/

ROR
https://ror.org/05k73zm37

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academy of Finland (Finland) ref: 132581

Alternative Name(s)
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Funder Name
Satakunta Hospital District, EVO (Finland) ref: 12/2010, 81096

Funder Name
South-West Hospital District, EVO (Finland) ref: 13893

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?
Results article	results	01/10/2015		Yes	No
Results article	results	09/11/2015		Yes	No
Results article	results	21/02/2017		Yes	No
Results article	results	12/07/2017		Yes	No