

Information technology in mental health

Submission date 07/12/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/01/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/09/2012	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

Not provided at time of registration

Study website

<http://users.utu.fi/mava/index2.html>

Contact information

Type(s)

Scientific

Contact name

Prof Maritta Välimäki

Contact details

Department of Nursing Science

Turku

Finland

20014

+358 (0)2 333 8495

mava@utu.fi

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

207384

Study information

Scientific Title

Evaluation of internet-based patient support system in mental health care: a randomised controlled cost-effectiveness analysis

Acronym

Mieli.Net

Study objectives

1. Does information technology (IT) affect patients' insight, quality of life, symptoms, compliance, knowledge of illness and its treatment, support treatment satisfaction, and independence or shore up opportunities for psychosocial functioning more effectively than written patient information or traditional information methods?
2. Does the use of IT in clinical practice improve the staffs' knowledge level and IT-related skills, attitudes towards technology use or affect staff co-operation and working methods?
3. What are the short and long-run costs of IT compared with written material and traditional methods used in clinical practice and does IT benefit the health care organisation and society more than the two other methods from the viewpoint of cost-effectiveness?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Pirkanmaa Hospital District approved on the 13th December 2004 (ref: ETL R01181)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Schizophrenia, schizotypal disorders or delusional disorders

Interventions

Staff in Group X will receive education (basic/advanced groups) on how to use computers, access internet-based services, and use IPSS during their educational sessions with patients. Only nurses in Group X have access to IPSS to avoid inter-group contamination. Staff in Group Y will be educated to manage education sessions with written/oral material only.

In patient groups, Intervention Group A will receive need-based computerised information during discussions with a staff member with five technology sessions each lasting about 20 - 60 minutes roughly twice a week. At the end of the session, patients will receive individualised leaflets. They will also be instructed on how to use IPSS after discharge. Patients in Comparison Group B will have five oral sessions on their education programs (no use of IT). The content, number and length of the sessions is the same as in Group A. Patients in Control Group C will receive standard care, i.e. no educational sessions will be offered and they receive written information (e.g. leaflets) according to ward standards.

Total duration of intervention was all together five education sessions after baseline measurement during one month and 1 - 2 sessions/week. Total duration of follow-up for all arms was 12 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Insight: The Schedule for the Assessment of Insight (SAI), measured at baseline (BL), 1, 3, 6 and 12 months

Secondary outcome measures

1. Quality of Life: Quality of life (the Quality of Well-Being, the Health Utilities Index, EQ-5D) and the Manchester Quality of Life Instrument (MANSA), measured at BL, 1, 3, 6 and 12 months
2. Symptoms: Semi-structured interview addressing psychiatric symptoms (Positive and Negative Syndrome Scale [PANNS]), measured at BL, 1, 3, 6 and 12 months
3. Compliance: Patients' compliance with treatment, patients' compliance with medication (Drug Attitude Inventory [DAI]), measured at BL, 1, 3, 6 and 12 months
4. Follow-up of medication adherence and treatment appointments (analysis of medical records)
5. Knowledge about illness and treatment: Knowledge test, measured at BL, 1, 3, 6 and 12 months
6. Treatment satisfaction during discharge process (Client Satisfaction Questionnaire-8 [CSQ-8]), measured at BL and before discharge
7. Disability and psychosocial functioning: symptoms disturbing work, social life, and family responsibilities (Sheehan Disability Scale) and the Global Assessment of Functional Scale (GAF), measured at BL, 1, 3, 6 and 12 months

In addition, drop-outs in each arm were analysed to estimate the acceptance of the interventions.

Overall study start date

14/03/2005

Completion date

04/10/2007

Eligibility

Key inclusion criteria

1. Aged 18 - 65 years, either sex
2. Diagnosis of schizophrenia, schizotypal disorders or delusional disorders (chapters F20 - F29, International Classification of Disease, version 10 [ICD-10])

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Unable to use the Finnish language
2. Unable to give written informed consent to participate

Date of first enrolment

14/03/2005

Date of final enrolment

04/10/2007

Locations

Countries of recruitment

Finland

Study participating centre

Department of Nursing Science

Turku

Finland

20014

Sponsor information

Organisation

Academy of Finland (Finland)

Sponsor details

Vilhonvuorenkatu 6

PL 99

Helsinki

Finland

00501

Sponsor type

Government

Website

<http://www.aka.fi/en-gb/A/>

ROR

<https://ror.org/05k73zm37>

Funder(s)**Funder type**

Government

Funder Name

The Academy of Finland (Finland) (ref: 207384)

Funder Name

The Jalmari and Rauha Ahokas Foundation (Finland)

Funder Name

The Finnish Cultural Foundation Uusimaa Regional Fund (Finland)

Funder Name

The Hospital District of Helsinki and Uusimaa (Finland)

Funder Name

The Pirkanmaa Hospital District (Finland)

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	01/06/2012		Yes	No