

Imagine your mood: a step towards personalized relapse prevention in depression

Submission date 14/11/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/12/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Major Depressive Disorder (depression) is a mood disorder that causes a persistent feeling of sadness and loss of interest. One of the options to reduce the burden of Major Depressive Disorder is to prevent it from coming back (relapse after remission). People diagnosed with recurrent Major Depressive Disorder have a very high risk of relapse after remission. Relapse prevention strategies for previously depressed people include continuing to take antidepressant medication and preventive psychological treatment. However, it is unclear what relapse prevention strategy works best for whom. The effect may be improved when interventions are tailored to specific people. Such personalization of treatment may be based on repeated assessments of a patient. More information is needed about differences in the risk of relapse, response to treatment, and how different relapse prevention strategies may target vulnerability for relapse. The aim of this study is to collect this information to inform personalized relapse prevention strategies. Repeated measurements in daily life using a smartphone application will be used to explore individual differences in vulnerability for relapse, and to explore what may work for whom to prevent relapse. The results may give new insights into individual differences in depression and ultimately may pave the way to tailored relapse prevention strategies.

Who can participate?

People aged 18 – 65 who have previously had depression and are taking antidepressant medication, and healthy volunteers who have never had depression

What does the study involve?

Previously depressed participants are randomly allocated to one of the three groups. Participants assigned to the first group continue taking antidepressant medication. Participants assigned to the second group taper (reduce) their antidepressant medication and attend eight sessions of preventive cognitive therapy. Participants assigned to the third group receive preventive cognitive therapy and continue taking antidepressant medication. All previously depressed participants are monitored over a 24-month follow-up period. The smartphone application “Imagine your mood” has been developed specifically for this study to assess the participants’ emotions and behavior in daily life. A trained research assistant installs the “Imagine your mood” application on the smartphone of the participants. Participants are instructed to fill out questionnaires in response to triggers that are set at 10 random moments

throughout the day, for 3 days a week during the first 8 weeks of the study (parallel to the 8-week preventive cognitive therapy period). The same data is also collected from the healthy volunteers during an 8-week period.

What are possible benefits and risks of participating?

All previously depressed participants will be monitored for depressive relapse and informed in case of a depressive relapse, so that they can contact their GP or psychiatrist. Participants who receive preventive cognitive therapy may potentially benefit from it in terms of reduced risk of relapse. Participants who are allocated to tapering of antidepressant medication may potentially benefit from a reduction of side-effects of the antidepressant medication. How tapering of antidepressant medication influences the risk of relapse is unclear. For all participants, taking part in the study will cost time and effort.

Where is the study run from?

University of Groningen (Netherlands)

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

September 2012 to June 2017

Who is the main contact?

Prof. Claudi Bockting

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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

NL 24000.097.08

Study information

Scientific Title

Using app-based Experience Sampling Methodology to explore processes of change in a randomized controlled (micro) trial on relapse prevention interventions for recurrent depression

Study objectives

The aim of this study is to gain understanding of individual (affective) differences and processes of change that may inform personalized relapse prevention. To this end, Experience Sampling Methodology (ESM) will be used to explore affect in the daily life of previously depressed individuals randomized to different relapse prevention strategies. Additionally, a group of matched never depressed controls will be included.

Research questions:

1. Can individual differences in affect and within-individual affective change be discerned and do these signal future relapse?
2. How are (cognitive) mechanisms related to (affective) vulnerability?
3. Do early affective responses predict who will be able to taper antidepressant medication (ADM)?
4. Do relapse prevention strategies may differentially alter vulnerability for relapse?

Ethics approval required

Old ethics approval format

Ethics approval(s)

This micro-trial was conducted in a subset of patients that were included in the RCT "Disrupting the rhythm of depression" (Netherlands Trial Register: NTR1907). The addition of ESM to this RCT "Disrupting the rhythm of depression" was approved by the medical ethical board of University Medical Center Groningen, Groningen, 22/11/2013, ref: METc 2009/158. In addition, a group of matched healthy volunteers was included. Ethical approval for including these never-depressed individuals was obtained from the University of Groningen Ethical Committee of the Psychology Department, 22/10/2014, ref: ppo-014-043.

Study design

Single-blind randomised controlled 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Recurrent major depressive disorder

Interventions

Previously depressed participants will be randomly assigned to:

1. Preventive cognitive therapy (PCT) while continuing ADM (PCT + ADM)
2. PCT while tapering ADM (PCT – ADM)
3. Continuation ADM (ADM) control group

Participants in the PCT + ADM and PCT – ADM groups will receive eight weekly sessions of individual PCT. In the PCT – ADM group, participants will be instructed to gradually taper ADM in four weeks guided by their GP or psychiatrist, who will also be informed and advised. In the continuation ADM group and in the ADM + PCT group, participants and their GPs or psychiatrists will be advised to continue ADM.

Intervention Type

Mixed

Primary outcome measure

Given that this is an exploratory study on processes of change, there are no primary outcome measures defined.

To examine the research questions, the following measures will be used:

1. Affect, mood and mental imagery, collected using ESM. The experience sampling app “Imagine your mood” has been developed and programmed using TEMPEST software. The application has been programmed to set triggers for questionnaires 10 times a day, 3 days a week (on Thursdays, Fridays and Saturdays), for 8 weeks, resulting in a maximum of 240 completed responses. The triggers are set semi-randomly, between the hours of 7.30 and 22.30, with a maximum of one trigger per 90-minute interval and a minimum of 30 minutes between triggers. The ESM procedure will take place during the first 8 weeks of the study (parallel to the 8-week therapy period for previously depressed individuals who have been randomly assigned to receiving preventive cognitive therapy)
2. Relapse/recurrence over a follow-up period of minimal 15 months, using DSM-IV-TR criteria as assessed by the Structural Interview for DSM-IV (SCID, telephonic version) at 3 months, 9 months, at 15 months and at 24 months (current depressive symptomatology and previous 3, 6 or 9 months)
3. The ADM dose, assessed weekly during the ESM study period by telephone interviews

Secondary outcome measures

The following measures will be included for hypothesis-generating purposes:

1. Qualitative information on the use of the app, assessed in weekly phone calls during the 8-week ESM study period
2. Additional questions in the app questionnaire, assessed during the 8-week ESM study period (10 times a day, 3 days a week) using the experience sampling app “Imagine your mood”:
 - 2.1. Questions on the impact of ESM

- 2.2. Further assessment of participants mental representation
- 2.3. Physical complaints
- 2.4. Current and previous activities and future events
- 3. Additional measures assessed in the trial 'Disrupting the rhythm of depression' as described in the study design and protocol (Netherlands Trial Register: NTR1907).

Overall study start date

01/09/2012

Completion date

01/06/2017

Eligibility

Key inclusion criteria

Previously depressed participants:

1. A diagnosis of remitted MDD, with at least two previous depressive episodes in the past five years.
2. A current score of <10 on the Hamilton Rating Scale for Depression (HRSD)
3. Use of continuation ADM in the last six months before the start of the study
4. Age between 18 and 65

Healthy volunteers:

1. Age between 18 and 65
2. Match the previously depressed sample on age and gender

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Total previously depressed: N = 45, equally distributed over the three groups (15 per group).

Total matched healthy volunteers: N = 15

Key exclusion criteria

Previously depressed participants:

1. Current mania or hypomania or a history of bipolar illness
2. Any psychotic disorder (current and previous)
3. Organic brain damage
4. Alcohol or drug misuse
5. Predominant anxiety disorder
6. Current psychotherapy (> twice a month).

Healthy volunteers:

1. Current or previous depressive episodes
2. Use of ADM.

Date of first enrolment

01/01/2014

Date of final enrolment

31/01/2015

Locations

Countries of recruitment

Netherlands

Study participating centre

University of Groningen - Clinical Psychology Department

Grote Kruisstraat 2/1

Groningen

Netherlands

9712TS

Study participating centre

GGZ Drenthe

Stationsstraat 20

Emmen

Netherlands

7801 CG

Study participating centre

University Center of Psychiatry Groningen

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Sponsor information

Organisation

NWO - Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation,
Dutch National Science Foundation

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Sponsor type

Research organisation

Website

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Organisation

ZonMW - The Netherlands Organisation for Health Research and Development

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Sponsor type

Research organisation

Website

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Organisation

Netherlands Organisation for Scientific Research

Sponsor details

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Netherlands
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Sponsor type

Government

Website

<http://www.nwo.nl/>

ROR

<https://ror.org/04jsz6e67>

Funder(s)

Funder type

Research organisation

Funder Name

Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Alternative Name(s)

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, Dutch Research Council, Netherlands, NWO

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

01/06/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Claudi Bockting (C.L.H.Bockting@uu.nl)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/07/2017		Yes	No
Results article	results	01/07/2018		Yes	No
Results article	results	01/08/2018		Yes	No
Results article	secondary analysis from individuals with remitted recurrent depression	22/11/2023	19/12/2023	Yes	No