TITLE

Adaptation of a Behavioral Activation Treatment to Treat Depression in Autistic Adults

NCT number

NCT06064422

DOCUMENT DATE

12/26/2023

RUTGERS
UNIVERSITY | NEW BRUNSWICK

Graduate School of Applied and Professional Psychology
Rutgers University–New Brunswick
152 Frelinghuysen Road
Piscataway, NJ 08854-8020

http://gsappweb.rutgers.edu

Phone: 848-445-2000
Fax: 732-445-4888

CONSENT TO TAKE PART IN A RESEARCH STUDY
Phase 2: Feasibility Trial

FOCUS PARTICIPANT

Title: Adaptation of a Behavioral Activation Treatment to Treat Depression in Autistic Adults

Principal Investigator: Vanessa Bal, PhD

STUDY SUMMARY: This consent form is part of the informed consent process for this research study and provides information that will help you decide if you want to take part in this study.

The purpose of this study is to adapt a Behavioral Activation treatment (BeatIt) for autistic adults and evaluate its feasibility and acceptability. BeatIt is intended to help adults manage low mood. BeatIt has been shown to be useful for treating depression in adults with intellectual disability, but its utility has not yet been specifically tested for autistic adults.

If you take part in the research, you will be asked to complete questionnaires and participate in multiple visits to complete assessments and the intervention sessions. Your participation will span a period of approximately 22 weeks.

Some risks or discomforts that you may experience include frustration or psychological distress when completing surveys or trying new activities. Other risks include a loss of confidentiality if there is a breach in data security or if the study team has concerns that you are at high risk of harming yourself or others. Should this occur, we will be legally obligated to inform emergency services, which may cause you to experience psychological discomfort.

You may achieve individual benefits, including improvement in clinical symptoms (e.g., depression, anxiety). However, positive gains can never be guaranteed. You may not receive any direct benefit from taking part in this study.

An alternative to taking part in the research study is not to take part in it.

The information in this consent form provides more details about the research study and what will be asked of you if you choose to take part in it. You should feel free to ask any questions that you have either now or during the study, if you choose to take part. You should expect to be given answers you completely understand.

After all of your questions have been answered, if you wish to take part in this study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

RUTGERS
UNIVERSITY | NEW BRUNSWICK

Graduate School of Applied and Professional Psychology
Rutgers University–New Brunswick
152 Frelinghuysen Road
Piscataway, NJ 08854-8020

http://gsappweb.rutgers.edu

Phone: 848-445-2000
Fax: 732-445-4888

Who is conducting this research study?
Vanessa Bal, PhD is the Principal Investigator of this research study. A Principal Investigator is responsible for the study and how it is conducted. There are also other people who help conduct the study, which will be referred to as "the study team".

Dr. Bal may be reached at:
(848) 445-2300
604 Allison Road
Piscataway NJ, 08854-8001

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
This study is being done to adapt a Behavioral Activation treatment (BeatIt) for autistic adults. BeatIt is intended to help adults manage low mood and/or depression. BeatIt has been shown to be useful for treating depression in adults with intellectual disability, but its utility has not yet been specifically tested for autistic adults. Because we want to adapt this intervention for autistic adults, we are interested in 1) what changes need to be made to the current BeatIt treatment, 2) whether BeatIt can be done with autistic adults (feasibility), 3) what autistic adults and their support person think about BeatIt (acceptability), and 4) whether BeatIt is effective for helping autistic adults cope with low mood and/or depression. Results from this study will be used to inform adaptation to the intervention and planning for future studies to further explore its effectiveness.

Who may take part in this study and who may not?
Adults who 18 years of age and above, have a previous diagnosis of an autism spectrum disorder (ASD) and are currently experiencing clinically significant levels of depression. Adults may choose to also have 1-2 support persons participate in the study.

Why have I been asked to take part in this study?
You have been invited to participate in this study because you:

- Expressed interest via our screening form (by self or through a parent/guardian)
- Have a previous diagnosis of ASD
- Are experiencing depressive symptoms

What will I be asked to do if I take part in this study?
If you choose to participate in the study, the following is what will happen:

- **Baseline questionnaires and assessment visit**
  - You will complete an online set of questionnaires that ask about you, your thoughts, feelings, and experiences. Questionnaires are estimated to take 1 hour to complete.

Graduate School of Applied and Professional Psychology
Rutgers University–New Brunswick
152 Frelinghuysen Road
Piscataway, NJ 08854-8020
http://gsappweb.rutgers.edu
Phone: 848-445-2000
Fax: 732-445-4888

  - You will also complete an in-person assessment (interviews, activities) with our study staff. You will be asked to complete a brief assessment of problem solving abilities and asked further questions about your feelings and experiences. This visit will be approximately 2 hours long.
  - You may choose to identify a support person who is willing to participate in the study. A support person is any adult who knows you well and who you are comfortable having participate in the intervention with you. This may be a family member, friend, or other person who you feel will be able to support you.
  - A member of the study team will contact you within 2 weeks after your assessment to confirm if you are eligible to continue with the study and participate in the group.
- **12 treatment sessions**
  - You will complete 12 treatment sessions with the study staff and your support person (if applicable). Before each session you will complete a brief set of questionnaires about your mood and activities in the prior week. During the session, you will further discuss your mood and activities in the last week. The study staff will help you and your support person to identify and troubleshoot barriers to activities and make a plan for the next week. Each session will be approximately 60-90 minutes long.
  - **Feedback:** some focus participants and supporters will be asked to provide session feedback for approximately 5 minutes at the end of each session.
- **Midpoint questionnaires and visit**
  - After session 6, you will complete questionnaires to report on your thoughts, feelings, and experiences and a brief interview. The questionnaires are estimated to take 1 hour to complete and the interview approximately 30 minutes.
- **Outcome questionnaires and visit**
  - After the 12 treatment sessions, you will complete questionnaires and participate in an interview with a member of the study staff. You will report on your thoughts, feelings, and experiences, as well as your thoughts on BeatIt and your experience participating in the study. Questionnaires will take approximately 1.5 hours and the interview will take approximately 1 hour.
- **Follow-up questionnaires and visit**
  - Approximately 6 weeks after your outcome visit, you will be asked to complete online questionnaires to report on your thoughts, feelings, and experiences. You will also be asked about your activities, use of treatment strategies since completing the intervention and any additional feedback they have regarding the BeatIt intervention. Questionnaires will take approximately 1 hour and the interview will take approximately 30 minutes.

Please note, times above are estimates and vary by participant. We will take brief breaks between activities and can take more breaks if you need them.

RUTGERS
UNIVERSITY | NEW BRUNSWICK

Graduate School of Applied and Professional Psychology
Rutgers University–New Brunswick
152 Frelinghuysen Road
Piscataway, NJ 08854-8020

http://gsappweb.rutgers.edu

Phone: 848-445-2000
Fax: 732-445-4888

It is okay if you are not sure about the answers to any questions; you can try to answer or tell us that you do not know. If you want help completing the questionnaires at any time during the study, someone from the study team or your support person can read the items to you. You can also tell them your response and we can record it on the online form for you. We can add time to do this during an in-person or videoconference visit.

Treatment sessions and midpoint, outcome and follow-up visits can take place via videoconference or in-person, based on your preference. If you choose in-person, we will discuss whether being seen at Rutgers or another community setting is best. If you would feel more comfortable having your support person present during the baseline, midpoint, outcome or follow-up visits, we can ask them to attend.

Additionally, you can expect the following:

- **Video Recording:** Your visits will be recorded for research and training purposes. This includes coding of your behavior and responses to questions, as well as training of the research team.
- **Future contact:** The research team may wish to contact you in the future, to clarify or provide additional information for this study, or to invite you to participate in other research studies. Giving your permission for the research team to contact you does not obligate you to answer any future questions–you always have the right to decline further participation in research.

How long will the study take and how many subjects will take part?
About 57 individuals and 62 support persons will take part in this study (119 people total). Up to 24 autistic adults and supporters will participate in focus groups and 95 autistic adults and supporters will participate in the intervention study. Participation in the intervention study will last a total of about 22 weeks.

What are the risks and/or discomforts I might experience if I take part in this study?

- You may experience discomfort or psychological distress when completing surveys and answering questions about your thoughts, feelings, and experiences.
- We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy.
    - Your support person will be aware of personal information that you share during visits.
    - Your personal information may be given out if required by law. For example, if the study team has concerns that you are at risk for harming yourself or someone else, we may be required to disclose information about you to other doctors or the police.
- Authorized representatives from Rutgers University or funding agencies may review your research data for the purpose of monitoring or managing the conduct of this study.

Are there any benefits to me if I choose to take part in this study?

Graduate School of Applied and Professional Psychology
Rutgers University–New Brunswick
152 Frelinghuysen Road
Piscataway, NJ 08854-8020
http://gsappweb.rutgers.edu
Phone: 848-445-2000
Fax: 732-445-4888

You may achieve individual benefits, including improvement in depressive symptoms. However, positive gains can never be guaranteed, even in clinical services, and therefore cannot be guaranteed as part of this research study.

You may also feel benefit from contributing to research that has the potential to advance understanding of individuals with ASD and services to support their needs. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
Your alternative is not to take part in this study. If you want treatment for depression or other difficulties, we will provide community resources where you can inquire about possible clinical services.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study, you will be contacted.

Will I receive the results of the research?
You will not receive the results of the research.

Will there be any cost to me to take part in this study?
There will be no cost to you to take part in this study. You will be responsible for costs associated with traveling to Rutgers University.

Will I be compensated to take part in this study?
You will be compensated:

- $50 for the baseline questionnaires and assessment visit
- $25-50 for the midpoint questionnaires (depending on time taken)
- $50 for the outcome questionnaires and visit
- $25 for the follow-up questionnaires and visit (depending on time taken)

In sum, you will receive a maximum of $200 for your completion of assessment visits. All payments will be in the form of gift cards. You will receive compensation at the end of your participation.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential. If information from this study is published or presented at scientific meetings, your name and other personal and identifying information will not be used. Participation in research involves some risk of loss of privacy and total confidentiality cannot be guaranteed. Your personal information may be given out as required by law, our institution or funding agencies.

RUTGERS
UNIVERSITY | NEW BRUNSWICK

Graduate School of Applied and Professional Psychology
Rutgers University–New Brunswick
152 Frelinghuysen Road
Piscataway, NJ 08854-8020

http://gsappweb.rutgers.edu

Phone: 848-445-2000
Fax: 732-445-4888

We will use secure, password-protected websites, to collect and forward your responses to us. Only study staff will have access to these databases. To protect your identity, we will remove all information that could identify you, such as your name, address and phone number and replace it with the unique identifier before sharing any data with qualified researchers who have permission to access the LifeSPAN Lab Database.

Confidentiality may be broken if research staff determines that a child or dependent adult is being abused or neglected or if research staff determines that you are at imminent risk of harming yourself or someone else. If information you share during your visits suggests that you are at serious risk of harming yourself, we may have to break confidentiality to ensure your safety. In these cases, we may share info with the following groups:

- Provided Emergency or Clinical Contact(s)
- Local Police or Emergency Services

In such cases, you will be asked to go to the emergency department or someone may come to your residence to help ensure your safety.

What will happen to my information collected for this research after the study is over?
All study data will be stored indefinitely in the LifeSPAN Lab Database, a password-protected database maintained in a secure, password protected website or an encrypted device. De-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

What will happen if I do not wish to take part in the study or if I later decide to not stay in the study?
You may choose either to take part or not to take part in the study.

If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits. You can still get your care from our institution the way you usually do.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Bal at 604 Allison Road, Piscataway, NJ 08854-8001. Data that has already been published or sent to approved research collaborators may not be able to be withdrawn, but data would be withdrawn from all future uses as of the date the written request is received.

At any time, the researchers can discontinue your participation in this study because it would not be in your best interest to stay in it.

Who can I call if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor, Vanessa Bal, PhD at (848) 445-2300.

RUTGERS
UNIVERSITY | NEW BRUNSWICK

Graduate School of Applied and Professional Psychology
Rutgers University–New Brunswick
152 Frelinghuysen Road
Piscataway, NJ 08854-8020

http://gsappweb.rutgers.edu

Phone: 848-445-2000
Fax: 732-445-4888

If you have any questions about your rights as a research subject, you may contact the Rutgers University, Arts and Sciences Institutional Review Board:

Institutional Review Board
Rutgers University, the State University of New Jersey
Liberty Plaza / Suite 3200
335 George Street, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-2866
Email: human-subjects@ored.rutgers.edu

RUTGERS
UNIVERSITY | NEW BRUNSWICK

Graduate School of Applied and Professional Psychology
Rutgers University–New Brunswick
152 Frelinghuysen Road
Piscataway, NJ 08854-8020

http://gsappweb.rutgers.edu

Phone: 848-445-2000
Fax: 732-445-4888

AGREEMENT TO PARTICIPATE

If you do not wish to take part in the research, close this website address. If you wish take part in the research, please mark the statement below:

- ☐ I acknowledge that I am 18 years of age or older and have read and understand the information. I agree to take part in the research, with the knowledge that I am free to withdraw my participation without penalty.
- ☐ I acknowledge that if the study team is concerned that the I am at imminent risk for self-harm, they will follow procedures outlined above, which may include breaking confidentiality to ensure my safety (e.g., calling 911).
- ☐ I acknowledge that the study team has my permission to contact my support person, who will have the option to consent to participating in this study.

If you wish to be contacted for future research, please read and acknowledge the following statements. This is optional (not required for participation):

- ☐ I acknowledge that the study team has my permission to contact me for future research studies. I understand that I always have the option to decline participation in future studies and can ask to be removed from the contact list.

Electronic signature:_____Date:_____
Was a witness present? [Yes or No]
[If yes]
Witness to Consent Process
I have observed the consent process which included a description of the purposes and procedures of this Study and an opportunity for questions and answers about this Study. I attest that I am not a person involved in the design, conduct or reporting of the research study, and that the requirements for informed consent to the research have been satisfied.

Name of Witness (Type): _____
Electronic Signature: _____ Date: _____

By clicking "I Agree", I indicate that I have read this form and consent to participating in this research study.

I Agree | I Do Not Agree