# SWAT 213: Effects of providing information about enhancement treatment as usual on recruitment and retention to trials with autistic adults with depression

## Objective of this SWAT

To determine if providing information about enhancement to treatment as usual impacts autistic adults' perception of equipoise when consenting to randomisation and reduces the likelihood of attrition from treatment as usual in a randomised trial of a psychological intervention for depression.

To determine if providing autism awareness training to psychological therapists delivering treatment as usual affects therapists' perception of equipoise about psychological interventions for autistic adults and impact on their practice.

Study area: Randomisation, Retention

Sample type: Participants, Healthcare Professionals, Researchers

Estimated funding level needed: Low

# **Background**

Equipoise in randomised trials relates to the uncertainty principle i.e., that participants and researchers are unsure about which intervention will confer most benefit to participants. Participants can have a treatment preference before randomisation, and this can be based on perceived risks of the novel intervention, a general tolerance for novel interventions, concerns about side-effects or expectations of benefit for either intervention. A systematic review established however that there is no evidence that treatment preferences influence attrition in trials.(1)

In an earlier feasibility randomised trial of guided self-help for depression in autism, a greater proportion of participants withdrew or were lost to follow-up from the treatment as usual (TAU) arm than the new intervention arm (Guided Self Help: GSH).(2) In some instances, withdrawal was contingent on the outcome of randomisation to TAU. Some participants expressed the view that they had joined the study to access therapy specifically tailored for autistic people because they had prior negative experience of TAU.(3) In brief, several participants who took part in the interviews did not hold a view of clinical equipoise.

Randomised trials using TAU or existing practice as the comparator arm for a new intervention are subject to potential participants' views about and expectations of TAU. Where TAU is perceived as inadequate, this can raise ethical and clinical issues as well as impact on participants' perceptions of equipoise and affect recruitment and retention to the study. TAU for mild-moderate depression includes low-intensity cognitive behavioural interventions, ordinarily delivered by Increasing Access to Psychological Therapies (IAPT) services. However, working with autistic people is not included in the core training curriculum for IAPT practitioners. Furthermore, cognitive behavioural therapists report a lack of confidence in adapting their practice to meet the needs of autistic people,(4) and autistic adults report barriers to accessing psychological therapy services, specifically a lack of therapist knowledge about autism and therapist unwillingness/inability to adapt their practice.(5) It is plausible that TAU for mild-moderate depression is perceived as less than optimal by autistic adults and TAU therapists.

Based on published studies about autistic adults' experiences of accessing psychological therapy and the findings of the ADEPT feasibility study (ISRCTN54650760), it is considered appropriate to enhance TAU for the proposed full-scale randomised trial (ADEPT-2, ISRCTN17547011). This trial aims to investigate the effectiveness and cost-effectiveness of GSH and to evaluate the impact of this enhancement on perceptions of equipoise.

The aim of this study within a trial (SWAT) is to increase participants' perception of equipoise in ADEPT-2 by providing participants with information about enhancements to TAU before randomisation. The enhancements will comprise the provision of training resources for TAU psychological therapists, which will provide information about how to adapt standard CBT practice to meet the needs of autistic adults. The training resources will not include training in the GSH intervention or in working with depression specifically. They will comprise training materials about

generic adaptations to CBT practice and closely match the foundation training resources available to the GSH therapists. Therapists accessing the training resources will be invited to take part in a survey before and after access to evaluate the acceptability and perceived usefulness of the resources. Consent will be sought to contact therapists five months after access to complete a survey about the impact of the training on their clinical practice with autistic clients. They will also be invited to a focus group to consider this in more detail.

## Interventions and comparators

Intervention 1: Information about the provision of training resources to TAU psychological therapy services will be included in the Participant Information Leaflet (PIL) for ADEPT-2.

Intervention 2: Training resources in adapting CBT practice for autistic people will be offered to psychological therapy services (including NHS talking therapies for anxiety and depression) in England and Wales where ADEPT-2 is taking place. These services form a key element of the TAU arm in ADEPT-2. The training resources will provide information about how to adapt standard CBT practice to meet the needs of autistic adults. The resources will comprise 4 x 20-minute videos hosted on the ADEPT-2 website which can be accessed as self-directed learning. The training resources will not include training in the GSH intervention or in working with depression specifically. They will comprise training materials about generic adaptations to CBT practice and closely match the foundational training resources available to the GSH therapists.

Index Type: Participant Information

## Method for allocating to intervention or comparator

#### **Outcome measures**

Primary: Quantitative: Distribution of randomisation preference expressed by participants in ADEPT-2.

Qualitative: Reasons for randomisation preference, including the impact of any information in the PIL that influenced this (included in the larger qualitative study topic guide) Secondary: Quantitative

- TAU therapist uptake of the training resources measured by number of times the resources are accessed (website traffic)
- Therapist satisfaction with the training resources (survey following access)
- Therapist confidence in working with autistic people as measured by the Adapted Therapist Confidence Scale

### **Analysis plans**

Information gathered from the therapist survey will be analysed using descriptive statistics in respect of frequency of survey access and therapist demographics in using the survey. Pre-post-change in therapist confidence will be investigated using repeated measures ANOVA. Responses to open-text survey items enquiring about helpful aspects of the therapist training resources and further areas suggested for training will be analysed using content analysis. Thematic analysis will be used to understand the therapist experiences of using the training in practice as captured by the focus groups. This analysis will be conducted using a data driven inductive approach, and following the steps outlined by Braun and Clarke.(6) Data analysis will be conducted in tandem with data collection, and the topic guide may be amended based on early findings to ensure that a rich dataset is developed from the focus groups.

#### Possible problems in implementing this SWAT

Uncertainty about the extent to which TAU therapists will access the training resources. Continuing Professional Development can be prescribed in NHS talking therapies services with a need to upskill across a range of clinical topics and limited time in therapists' schedules to enable this. Accessing self-directed learning resources about adapting CBT practice for autistic people may not be a priority for CPD for services and therapists. This means that information provided to the ADEPT-2 participants cannot be definitive.

There is also a lot of information about the study contained in the PIL and it might not be possible to answer the question clearly, as the information provided in the PIL requires nuanced presentation.

#### References

- 1. King M, Nazareth I, Lampe F, Bower P, Chandler M, Morou M, et al. Conceptual framework and systematic review of the effects of participants' and professionals' preferences in randomised controlled trials. Health Technology Assessment 2005;9(35):1-186, iii-iv.
- 2. Russell A, Gaunt DM, Cooper K, Barton S, Horwood J, Kessler D, et al. The feasibility of low-intensity psychological therapy for depression co-occurring with autism in adults: The Autism Depression Trial (ADEPT) a pilot randomised controlled trial. Autism 2020;24(6):1360-72.
- 3. Horwood J, Cooper K, Harvey H, Evans L, Russell A. The experience of adults accessing adapted Cognitive Behaviour Therapy: ADEPT (Autism Depression Trial) qualitative evaluation. Research in Autism Spectrum Disorders 2021;86:101802.
- 4. Cooper K, Loades ME, Russell A. Adapting psychological therapies for autism. Research in Autism Spectrum Disorders 2018;45:43-50.
- 5. Adams D, Young, K. A systematic review of the perceived barriers and facilitators to accessing psychological treatment for mental health problems in individuals on the autism spectrum. Review Journal of Autism and Developmental Disorders. 20218(4):436-53.
- 6. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology. 2006;3:77-101.

# Publications or presentations of this SWAT design

## **Examples of the implementation of this SWAT**

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