

SWAT 220: Impact of an inclusive recruitment animation (developed with PPI input) on recruitment of UK ethnic minority participants in a trial for young people at risk of bipolar disorder

Objective of this SWAT

To evaluate the impact of the introduction of an inclusive recruitment animation on referrals and recruitment of UK ethnic minority participants into the BART-II trial.

Study area: Recruitment

Sample type: Participants, Patients

Estimated funding level needed: High

Background

It is important that all members of the potentially eligible population for clinical trials and research are identified and then approached to allow them to consider taking part in the study. However, UK ethnic minority groups are under-represented both in clinical and research populations. Multiple factors are cited as drivers of this under-representation, including referral routes, inaccessibility of health care, stigma, systemic factors, professionals' beliefs, language and mental health literacy.[1]

The BART-II randomised trial (ISRCTN13363197) will test an adaptation of cognitive behavioural therapy (CBT) for young people (aged 16-25 years) identified as being at risk of bipolar disorder: This adaptation is called CBTBAR. The trial has five recruiting sites in Greater Manchester, Sheffield, Lancashire, Birmingham and Norfolk, with local populations that differ in both the proportion and diversity of people from ethnic minority groups. The recruitment strategy for BART II uses outreach principles where participants are seen in non-stigmatising settings and least restrictive venues, such as youth centres, colleges, and primary care and health settings. Furthermore, recruitment involves casting the net into a variety of established mental health services, as well as school and university health services, other youth services and the voluntary sector.

BART, the feasibility trial that informed BART-II, did not have good representation of the ethnic minority population at the recruitment site and it is hoped that adoption of inclusive recruitment materials might improve participation from ethnic minority groups in BART-II. Therefore, we are working with a PPI group made up of young people who belong to UK ethnic minority groups in order to co-produce an inclusive animation. This SWAT will explore whether this inclusive, co-produced animation will improve referrals and recruitment of young people from UK ethnic minority groups for BART-II.

Interventions and comparators

Intervention 1: Standard recruitment without the use of any animation video. Introduced from recruitment month 1.

Intervention 2: Standard recruitment strategy using Animation Video 1 only, which was developed by the host trial PPI group made up of young people at risk of bipolar disorder who took part in the previous BART trial. This will be used by all participating sites and across all platforms previously used for dissemination (website, YouTube, social media). Introduced from recruitment month 6.

Intervention 3: Recruitment using both Animation Video 1 (host trial) and Animation Video 2 (inclusive). This animation will be launched at month 13 to all participating sites and across all platforms previously used for dissemination (website, YouTube, social media). The dissemination strategy for animation video 2 will be co-designed by the PPI group.

Index Type: Method of Recruitment, Participant Information

Method for allocating to intervention or comparator

Time period: sequential implementation of Animation Videos 1 and 2 (interrupted time series design)

Outcome measures

Primary: Proportion of all referrals in each site in each recruitment month who are from a UK ethnic minority group.

Secondary: Proportion of all recruits in each site in each recruitment month who are from a UK ethnic minority group; number of UK ethnic minority potential participants referred per month; number of UK ethnic minority participants assessed for eligibility per month; number of UK ethnic minority participants recruited per month; proportion of UK ethnic minority participants recruited per month who provide data for the host trial measure of mechanism (HAPPI scores at 4-month timepoint); proportion of UK ethnic minority participants recruited per month who provide data for the host trial co-primary outcomes (LIFE depression and LIFE mania 4-week average PSR scores (at 27 weeks post-randomisation)).

Analysis plans

The analysis will evaluate the primary and secondary outcomes as an interrupted time series, both graphically (percentages or numbers by month, as appropriate) and using appropriate segmented regression methods (e.g. interrupted time-series linear or Poisson regression using month as the unit of analysis, incorporating time trends and a step change corresponding to the introduction of animations 1 and 2, and with/without auto-correlated errors). Data will be analysed overall (adjusting for site) and by site. The outcomes will also be represented graphically (by month).

Possible problems in implementing this SWAT

A non-randomised design (interrupted time series) had to be used because it was not feasible to conduct a randomised SWAT because the recruitment strategy does not involve independent sites/clusters (some recruitment will be via social media, for example) and time was needed to create the inclusive animation video. Therefore, it is likely to be difficult to control for confounding factors, such as any temporal effects or changes in staff or service.

References

1. Dawson S, Banister K, Biggs K, et al. Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups practical guidance to support better practice. *Trials* 2022;23:672.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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