PROTOCOL

Internet-based intervention versus face-to-face clinical care for tinnitus: A randomized control trial

Clinical Trials registration number: NCT02665975

Principle Investigator: Eldré Beukes (eldre.beukes@anglia.ac.uk)

Ethical approval: Cambridge South Research Ethics Committee, 16/EE/0148. HRA approval under IRAS project identification number 195565

Sponsor: Anglia Ruskin University

Grant: British Society of Audiology Applied Research Grant Fund

Clinical Sites: Norfolk and Norwich University Hospitals NHS Foundation Trust

Hinchingbrooke Health Care HNS Trust

Milton Keynes University Hospital NHS Foundation Trust

Date of protocol version:10 Juy 2016

INTRODUCTION

Tinnitus places a burden on healthcare systems, leaving many people with distressing tinnitus without appropriated care. Innovative management strategies are required to improve access to evidence-based treatments. A guided Internet-based intervention for tinnitus was therefore developed (iCBT) for a UK population. Initial clinical trials indicated that iCBT in the UK is effective at reducing tinnitus distress and associated comorbidities. The aim of this randomized control trial is to compare this iCBT intervention to that of standard tinnitus care provided face-to-face in clinical settings, for reducing tinnitus distress and associated problems.

OBJECTIVES

The primary aim of this study is to evaluate the effectiveness of iCBT for tinnitus distress, compared to standard care. The key secondary objective is to determine the effectiveness of iCBT for tinnitus related comorbidities, compared to standard care. Further objectives are to determine the longer-term effects of iCBT compared to that of standard care, two months post-intervention and establish if there are any predictor variables associated with outcomes for iCBT compared to those for standard care.

STUDY DESIGN

A randomised, multi-centre, two-arm parallel group, non-inferiority trial with a sequential adaptive design and a two-month follow-up will be followed. The experimental group will receive eight weeks of guided internet-delivered treatment

(iCBT) as seen in Figure 1. The control group will receive a standard individual face-to-face audiological care. The hypothesis is that there will be no difference in outcomes for the treatment and control groups. These groups will be followed prospectively for two months, to establish the maintenance and effectiveness of both treatments on tinnitus distress.

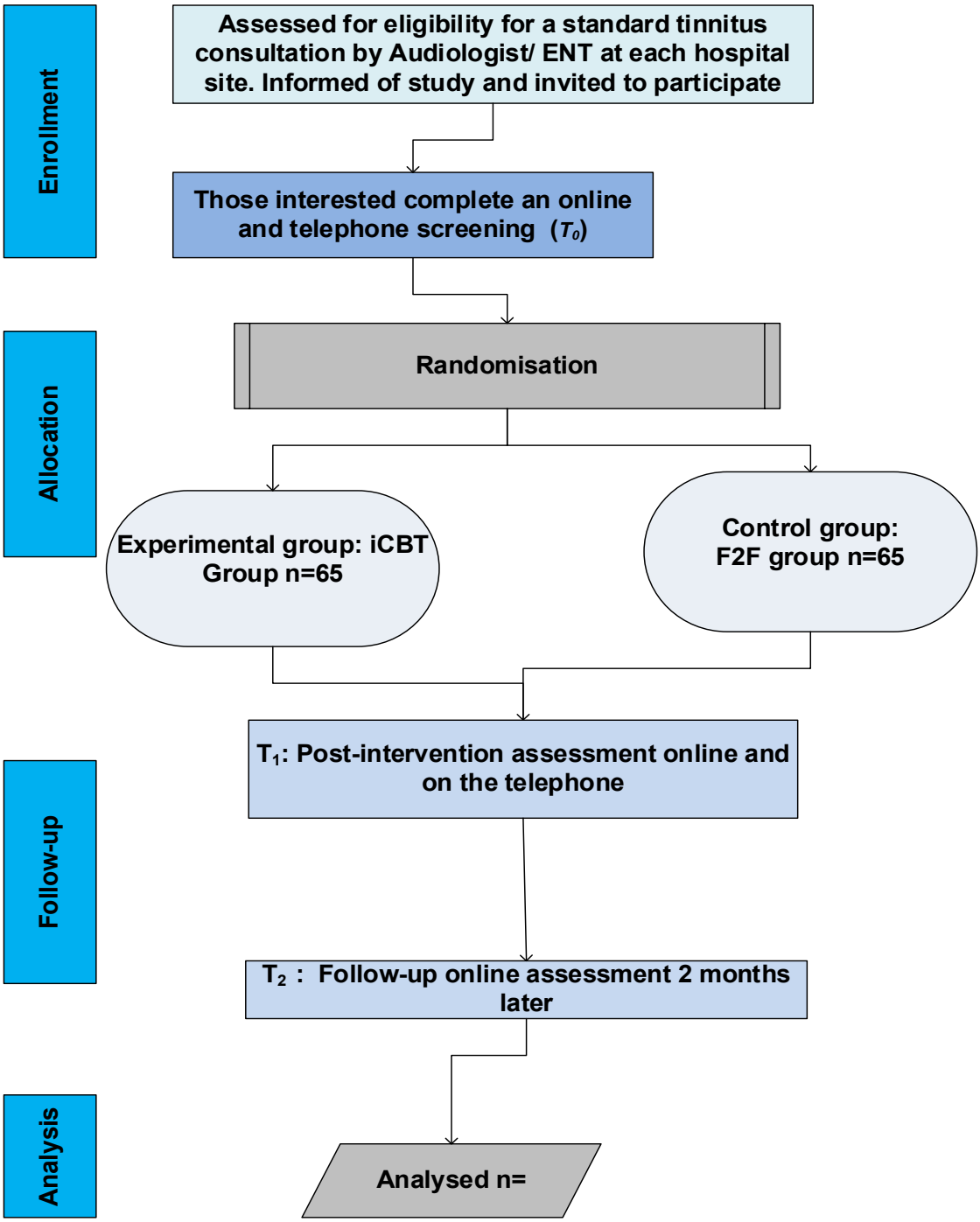

Figure 1: Trial design

PARTICIPANTS

Sample size

Sample size calculations have indicated that 65 participants are required per group. Estimated recruitment is 50 participants from both Norfolk and Norwich University Hospital and Hinchingbrookes Hospital and 30 from Milton Keynes University Hospital.

ENROLLMENT

All adult patients referred to the three participating Tinnitus Clinics during the recruitment period, who meet inclusion criteria, will be invited to participate. It is estimated that recruitment will occur over a two-month period. Eligibility is determined on the basis of the following criteria:

Inclusion Criteria

i) Having undergone a clinical evaluation by either their ENT Specialist or the Audiologist at participating sites, to rule out the presence of serious auditory pathology

ii) Experiencing tinnitus distress deemed to require a referral to the tinnitus clinic by the referring ENT Specialist or Audiologist

iii) Aged 18 years and over, living in the UK with the ability to read and type in English

iv) Regular access to a computer and the internet and the ability to use these

Exclusion Criteria

i) Reporting any major medical or psychiatric conditions

ii) Undergoing any tinnitus therapy concurrently to partaking in this study

Withdrawal

Participants will be informed of the right to withdraw without penalty. Statistical analysis will be done on an intention to treat basis unless they request all data removal.

SCHEDULE

Recruitment will be aimed to start in August, with initial participants from the face-to-face interventions to be seen between September 2016-January 2017 for their initial and follow-up appointments. Study close out will be two months after their intervention ended, which is estimated to be by April 2017. A broad outline of responsibilities is given in Table 1.

Table 1: Responsibilities of clinical sites and PI

Recruitment and distributing PIS	Clinical sites
Providing information about the study	Principle investigator (PI)
Study consent	Online (PI)
Assessment	Online. PI to pass on results to clinical sites
Initial telephonic contact with participants	PI
Randomisation and allocation	PI and PI to pass on allocation to clinical sites
Triage for the need for amplification	Clinical sites. Appointments to be considered on an individual basis

iCBT group: 8 weeks treatment	PI
Face to face standard care group treatment and appointment worksheet completion	Clinical sites
Post-intervention outcome measures	Online. PI to pass on results to clinical sites
Post treatment phone call	PI
Follow up assessment	Online. PI to pass on results to clinical sites

Data management

All personal data will be kept confidentiality. Each participant will be assigned a random user code (four digits followed by four letters), this is used by therapists to identify the participant during treatment. Secure communications to take place between clinicians and the therapist via the tackling tinnitus website, for which login details have been provided. All personal participant information to be saved safely according clinical sites IT policies.