

PARTICIPANT INFORMATION

Thank you for your interest in our research!

Before deciding whether to take part in the research, it is important you understand what it is for, and what it will involve. Please read the following information carefully and take your time to decide. If anything is unclear or if you would like more information before, during or after taking part, please email Fabio.zucchelli@uwe.ac.uk or heidi3.williamson@uwe.ac.uk or call them on 0117 3283882.

Who is running the study?

This research study is being carried out by researchers at the [Centre for Appearance Research](#) based at the University of the West of England, Bristol (UWE Bristol).

What is the study about?

The study is testing a smartphone-based self-management course called *ACT It Out*. The course is for adults who have a visible difference and are experiencing psychological and/or social difficulties to do with appearance concerns. By a ‘**visible difference**’, we mean a physical appearance that you consider to be significantly different to a typical appearance. Causes of visible difference can include health conditions from birth (e.g. cleft lip and/or palate) or conditions developed later in life (e.g. skin conditions), following injury (e.g. burn scarring), or as a result of medical treatment (e.g. surgery for cancer). These do not cover all possible causes, however.

ACT It Out has been designed to help its users do more of the things they care about in life, and to reduce the impact of appearance concerns on their daily life. We would like to understand what it is like to use ACT It Out: specifically, how helpful it is, how much participants like using it, and if it is doing what it is designed to do.

ACT It Out was developed by UWE Bristol researchers together with people who have visible differences and charities (led by Vitiligo Support UK), specialist psychologists (led by Dr Olivia Donnelly from North Bristol NHS Trust) and mobile app experts. The 6-session course is based on an established psychological approach called Acceptance and Commitment Therapy (ACT) - hence its name *ACT It Out*. It is designed as a ‘low-level’ intervention, meaning **it is self-guided and does not involve real-time support from health professionals**. ACT It Out is not designed to take the place of professional face-to-face talking therapies, and is **not intended for people experiencing serious mental health difficulties**. It has a reading age of 12+.

The version tested in this study is an early “prototype” of a smartphone app. As such it has been developed on an existing online platform called Qualtrics® rather than an app that can be downloaded. The Qualtrics® prototype version of ACT It Out is designed to work as much like a smartphone app as possible.

Who can take part?

You can take part if you:

- Are aged 18 or older AND
- Are based in the UK AND
- Have a visible difference (please see the definition in the previous section, 3rd sentence) AND

- Are experiencing psychological and/or social difficulties to do with concerns about your visible difference. Common difficulties are social anxiety and/or withdrawal from social activities, receiving unwelcome attention from others, low mood, low self-esteem, body image concerns; (you may experience one, a few, or all of these difficulties) AND
- Own a smartphone (Apple, Android or Windows) with enough data allowance and/or Wi-Fi to regularly access the internet AND
- Have experience using smartphone apps AND
- Are able and willing, in principle, to commit to completing (a) six weekly sessions, each lasting around 30-mins (though they can be done in pieces) and (b) brief activities between each session (2-10-mins daily). Taking part does not mean you have to complete the entire course as completion is entirely voluntary.

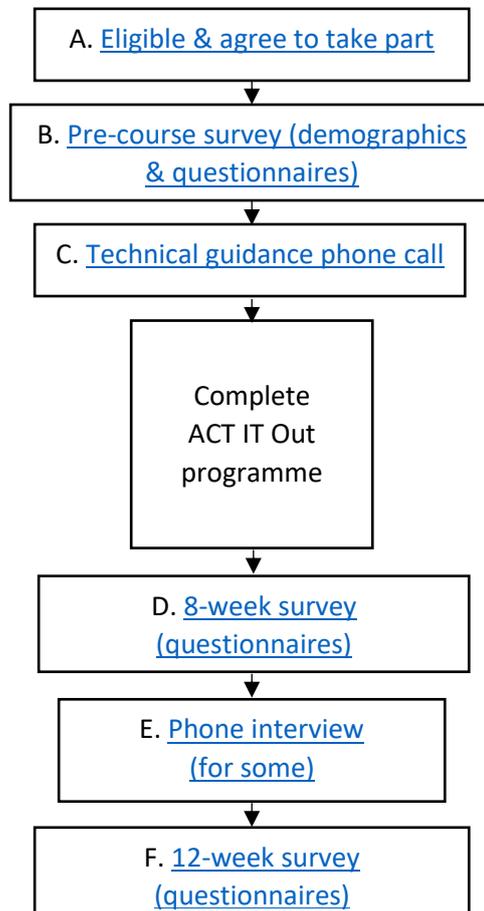
Unfortunately, because of who ACT It Out is designed for, you are **not** be eligible to take part if you:

- Have developed a visible difference as the result of a traumatic injury in the past 6 months OR
- Are experiencing **marked distress** / a mental health crisis, such as psychological trauma, severe low mood, suicidal thoughts, self-harm, or are feeling disconnected from reality OR
- Are currently going through any talking therapy or expect to be within the next 3 months OR
- Your primary appearance concerns are to do with weight and/or eating.

If you are unsure whether you are eligible to take part, please feel welcome to discuss this with the lead researcher (email Fabio.zucchelli@uwe.ac.uk or telephone 0117 3283882).

What does taking part involve?

This is how the process looks in summary, with more detail below:



A. If you are eligible and agree to take part, you will be invited to use the ACT It Out course (described above) on your smartphone.

B. Before using ACT It Out, we will ask you to complete an online survey consisting of (a) questions about your background (e.g. age, gender, ethnicity, cause of visible difference), followed by (b) a set of questionnaires that measure different aspects of appearance concerns and wellbeing. This should take around 15 minutes.

C. Also before using ACT It Out, we will invite you to speak via telephone with a researcher, who will give you technical guidance on how to use ACT It Out. This is recommended even for experienced smartphone users, as the Qualtrics® platform through which ACT It Out is accessed is unlike a downloaded commercial app, and we want to make sure all participants are aware of its safety features.

D. Eight weeks after starting ACT It Out, you will be asked to complete an online survey consisting of the same set of questionnaires as you completed before starting ACT It Out.

E. You may also be invited to take part in a telephone interview lasting up to 20-mins, in which we will ask you open questions about your experience of using ACT It Out. You may be invited if you have completed ACT It Out or whether you have stopped part way through (as we would also like to understand why you may have stopped). If you are invited for an interview, we will contact you via email. You can request to speak with a female or male. Participation in this interview is entirely optional.

F. To understand the longer-term effects of ACT It Out, we will also invite you to complete the same online survey after 12 weeks from starting the course.

Can I withdraw from the study?

You can stop taking part at any point of the study, without giving a reason. You can also choose not to answer certain questions in both the online surveys and the ACT It Out course. If you would like to withdraw any data you have already given, please email Fabio.zucchelli@uwe.ac.uk. You can withdraw your data up to 16 weeks after starting the study (4 weeks after the final survey), as we anticipate analysing the data at that point. Deciding to stop taking part or withdrawing your data from the study does not have any penalty. If you withdraw, we will destroy all email correspondence with you (both from 'Sent' and 'Deleted' item folders).

What data will I give?

Your mobile phone number:

To give the experience of reminder notifications possible in a real app, **researchers will send you personalised reminder text messages**. The timing and content of these messages will be based on the information you provide during ACT It Out sessions (e.g. you request a reminder be set for a specific goal at a date and time of your choosing). This means that **researchers will check the information you give in each session**. It also requires that **you provide your mobile number** (for the same handset that you use for ACT It Out). Researchers will send you text messages from a secure service endorsed by the UWE Bristol Information Technology service. We will also text you important technical updates if/when required about any problems with the Qualtrics® prototype platform.

Your answers to questions in the course:

Researchers will also look through the information you have given during ACT It Out sessions in order to check (a) participants' level of engagement and (b) for any information suggesting participants may be at risk of harm to themselves. In case the research team are concerned about your safety, they will send you a text message with support information.

What will happen to my data?

All the information you provide will be kept securely and confidential by the research team at the Centre for Appearance Research, UWE Bristol. **Your phone number and any other personal data will be permanently deleted** and all your other data will be anonymised 16 weeks (roughly 4 months) after you start the study (or deleted earlier should you request your data be withdrawn). Your data may be published in academic journals and presentations, but this data will not be identifiable.

Please see the UWE Bristol Privacy Notice for details of how data will be processed in accordance with the General Data Protection Regulation ([GDPR](#)).

What are the potential benefits and risks in taking part?

The ACT It Out course has been designed by experts to improve users' engagement in meaningful life activities, and lessen the impact of appearance concerns on daily life. While its ability to do so has not yet been tested, we can expect that by completing ACT It Out, you may experience psychological and/or social benefits to your daily life.

By completing ACT It Out and allowing UWE Bristol researchers to access your data, you will also be helping us to further improve the course. Our ultimate aim is to get funding to develop an openly available mobile app. This would allow many people with visible differences across the world to get this specialist help. Your involvement in this research study greatly helps us towards this goal.

Once you start ACT It Out, you will be given a £10 Amazon voucher to compensate you for any data usage not covered by your phone contract / pay-as-you-go service. After you have completed the 12-week follow-up survey, you will receive another £10 Amazon voucher as a thank you for completing the study.

Completing the questionnaires and especially going through the ACT It Out course will involve considering how you think and feel about your appearance, and how you behave in response to these thoughts and feelings. ACT It Out is designed to guide you in managing any intense/difficult thoughts and feelings that arise in this process. Indeed, many of the skill-building practises focus on this capacity.

Should any distress you experience be too much to manage, a "Get Help" button is accessible via the contents menu in the ACT It Out course. This provides details of support organisations. Otherwise, please do not hesitate to make use of any of the following sources of support:

- [Changing Faces](#) Advice and Support Helpline: 0300 012 0275 (10am – 4pm, Monday – Friday)
- [Samaritans Helpline](#): 116 123 (24 hrs, everyday)
- [Outlook Service](#) Specialist psychological support for appearance concerns relating to a visible difference (based in Bristol but accepts referrals from NHS England professionals including GPs): 0117 414 4888 (9am – 3pm, Monday – Thursday).
- For condition-specific support resources, check our [Sources of Support](#)
- Contact your general practitioner

We expect that people who will get most from the course are those who feel willing and able to engage with a self-guided course, are open to new approaches to self-management, have a support network (e.g. family or friends), and are able to safely bring personal experiences to mind (including difficult thoughts and feelings).

Who has ethically approved this study?

The project has been reviewed and approved by the University of the West of England University Faculty Research Ethics Committee (study reference HAS.20.01.114). Any comments, questions or complaints about the ethical conduct of this study can be addressed to the Research Ethics Committee at the University of the West of England at: Researchethics@uwe.ac.uk.