Daylight
Instructions for Use

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Introduction

Indications for Use

Daylight is a digital therapeutic intended to provide Cognitive Behavioural Therapy (CBT) for the improvement of worry and anxiety and treatment of Generalised Anxiety Disorder (GAD) in adults aged 18 years and older.

For otherwise healthy adults who have difficulty with worry and anxiety, Daylight may be utilised as a non-prescription self-help tool to improve overall mental health and wellbeing.

Benefits of Daylight

Research has indicated that individuals who use Daylight experience reductions in Generalised Anxiety Disorder (GAD) symptoms, worry, depressive symptoms, sleep difficulties, and improvements in overall wellbeing and quality of life. Research has also shown that the benefits of Daylight are maintained in the 6-month period following Daylight use.

Who should use Daylight

Daylight may be suitable for you if:

- You are 18 years and older

- You are experiencing difficulties with worry and anxiety

- You have been diagnosed with Generalised Anxiety Disorder

- You have stable mental and physical health

- You are able to read, hear, and understand English

- You have regular access to a mobile device

- You have periodic access to the internet

Who should not use Daylight?

To reduce risk, certain modifications to the Daylight programme may be required for certain populations. Please see the safety information and warning section on the following page.

Safety Information ⚠️

Safety Information and Warnings

Daylight does not provide crisis support. If you are experiencing a medical emergency, including suicidal thoughts, call NHS 111, call your GP, or go to your nearest A&E department.

Daylight contains sensitive medical information. Please protect your privacy by password protecting your computer, or phone and ensure that nobody else can access the device.

Daylight may not be suitable for individuals with certain mental health symptoms, such as thoughts of self-harm, suicide, or violence toward others; substance use problems; psychosis or mania; or symptoms that compromise thinking and decision-making (e.g., dementia or other cognitive impairments). If you experience any of these symptoms, consult with a doctor before using Daylight.

Worry and anxiety are very common in conjunction with a range of health conditions including cancer, pain, as well as during periods of hormonal changes (e.g., during and after pregnancy, menopause). There is good evidence that the CBT techniques within Daylight can help people improve their feelings of worry and anxiety even in the context of such health conditions. However, it is recommended that you consult with a doctor before using Daylight if you have an existing health condition, are pregnant or recently have been pregnant.

Daylight should not be used to address or process fears related to traumatic experiences or memories. Consult your doctor if you need help with difficulties related to trauma.

If you notice a worsening of your anxiety symptoms, please consult your doctor. Daylight techniques are based on cognitive behavioral therapy (CBT). A temporary increase in anxiety is common when beginning to use CBT techniques. Please consult your doctor if you continue to experience an increase in anxiety.

Daylight includes a technique called "Tense & Release" that involves tensing and relaxing your muscles. If you experience pain while tensing your muscles, you can modify this exercise (for example, by skipping the tensing of muscles) or skip it altogether.

Daylight includes a technique called "Facing Avoidance" that involves reducing unhelpful avoidance in response to anxiety. This technique should only be used in situations where you are not in real danger and shouldn't be practiced in situations that are dangerous or would put you at risk for harm.

Daylight is not a substitute for other medical or mental health treatment. The medical advice provided in Daylight should not be solely or primarily relied upon to treat psychiatric conditions. Please don't make any changes to your medications or treatment plan without consulting your doctor.

Daylight techniques are delivered in a visual and auditory format. If you have vision or hearing impairment, you may need to arrange appropriate assistance to help you complete techniques.

Daylight provides users an option to enable Multi-Factor Authentication (MFA) to make the app more secure. However, please note if you lose access to MFA after first enabling it, the Daylight team will not be able restore your access to MFA and you will lose your progress in the Daylight program and will have to start all over again at the beginning of the program.

Side Effects, Additional Resources

Side Effects

No serious adverse events have been reported in relation to use of Daylight. Research participants who utilised Daylight reported experiencing the following adverse events: low mood (60%), headache and/or migraine (60%), fatigue and/or exhaustion (59%), reduced motivation and/or energy (58%), feeling agitated (52%), difficulty concentrating and focusing on things (51%), feeling irritable (51%), difficulty remembering things (40%), bodily pain (39%), changes in hunger and/or appetite (39%), extreme sleepiness (32%), dizziness (17%) euphoria and/or intense increase in mood (15%), and blurred vision (6%; Carl et al., 2020).

Additional Resources for Generalised Anxiety Disorder

National Health Service

www.nhs.uk/mental-health/conditions/generalised-anxiety-disorder/overview/

Daylight

What is Daylight?

Daylight is a fully automated digital worry and anxiety improvement programme based on cognitive behavioural therapy (CBT) for Generalised Anxiety Disorder (GAD). GAD is a mental

health disorder characterised by excessive worry and anxiety that is difficult to control and is accompanied by related symptoms, such as tension, restlessness, fatigue, irritability, and significant distress or interference in functioning. While often initially triggered by a stressful life event, GAD is maintained by unhelpful behaviours and thoughts. Daylight targets these unhelpful behaviours and thoughts using evidence-based cognitive and behavioural interventions. Reducing these unhelpful behaviours and thoughts leads to a reduction in GAD symptoms.

Common behaviours maintaining GAD include avoiding situations and/or thoughts that are anxiety-provoking (e.g., procrastinating or trying not to think about a feared outcome), and/or engaging excessively in activities to try to reduce acute anxiety (e.g., seeking reassurance from others, "checking" things excessively, overplanning, etc.). Psychoeducation about the impact of these behaviours on anxiety (i.e., that these unhelpful behaviours may seem helpful but can actually maintain or worsen anxiety) is provided in Daylight, as well as techniques to target unhelpful behaviours, such as stimulus control (i.e., limiting worrying to a specific time and place) and imaginal exposure (i.e., facing, or not avoiding, worrisome thoughts and fears).

GAD involves excessive worrying, often with unhelpful thinking patterns that can involve catastrophizing, overgeneralizing, all-or-nothing thinking, jumping to conclusions, and emotional reasoning. Daylight addresses unhelpful thinking patterns using a cognitive technique called cognitive restructuring (i.e., identifying and challenging unhelpful thoughts), as well as introducing a physiological technique (applied relaxation) to help reduce tension and focus mental attention which can in turn relax the mind.

Recommended Use

In the Daylight programme, a virtual therapist will teach you scientifically backed techniques to reduce GAD symptoms. You will learn how each of the core techniques work in a "Lesson" (2-3 minutes), and practice each in a "Guided Practice" (approximately 5 to 10 minutes in length). After completing the "Guided Practice" for a given technique, you will be offered shorter (i.e., 2 to 5 minutes) practice versions of the technique, or you can repeat the Lesson or Guided Practice to review a technique. After completion of a Guided Practice, the Lesson for the next technique is immediately available. In addition, the Practice Library contains additional content options to vary your daily practice.

There are three main components to Daylight:

1. Learning the techniques in the core program sessions and additional bonus content

2. Practicing the techniques in the Practice Library (either by repeating Guided Practices or using shorter practice versions of the techniques), or using additional content in Practice Library)

3. Practicing the techniques on your own outside of Daylight

It is recommended that you give Daylight sessions your full attention and effort to ensure positive results, and that you do your best to incorporate these techniques into your daily life as instructed. Research shows that applying the techniques you learn to your real life and practicing them on your own leads to better outcomes.

At times, the programme will be challenging. Especially the final technique, Worry Exposure, which involves directly facing worrisome thoughts and fears. This technique is introduced last so that you can learn additional techniques to manage anxiety to prepare you to engage in this

activity. While facing worrisome thoughts and fears is challenging, it is one of the most powerful tools of the programme.

A final component of Daylight are weekly check-ins. Each week, Daylight will ask you to complete a series of questions to assess your progress and provide you with personalised guidance on how to further apply the techniques in the programme.

We recommend aiming to use Daylight daily (either in the programme or applying the techniques outside of the app in your life) for best results. Our research indicates that many people begin to see benefit after using the programme consistently (i.e., approximately daily) for 3 to 4 weeks. However, people tend to see more durable improvement after 6 weeks of regular use. You can use the weekly check-ins to assess your progress and determine what areas to focus on. Once your symptoms have improved, we recommend continuing to complete the weekly check-ins to keep monitoring your symptoms, as symptoms of GAD can come and go over time with stressful events. The techniques in Daylight can be repeated any time you experience an increase in symptoms or to refresh your learning.

Daylight is intended as a self-help programme. If you have learned all four techniques, have practiced them within the programme, have integrated the techniques into your daily life, and are still struggling with worry and anxiety, you may benefit from the help of a mental health professional. Please consult your doctor if this is your experience.

It is recommended that Daylight be accessed on a password protected device to reduce the risk of unauthorised access. Visit www.trydaylight.com/privacy to read our Privacy Policy.

User Instructions

Getting Started: Sign up and download the app

Sign up for Daylight through the link provided by your employer or health care provider. Answer each question, and select "Sign up" to create an account. Enter your name, email, and password to sign up.

Note: You may be asked to verify your benefit coverage by entering your employer identification or additional information.

Next, download the Daylight app from the Apple App Store or Google Play Store from your mobile device, and login with your email and password.
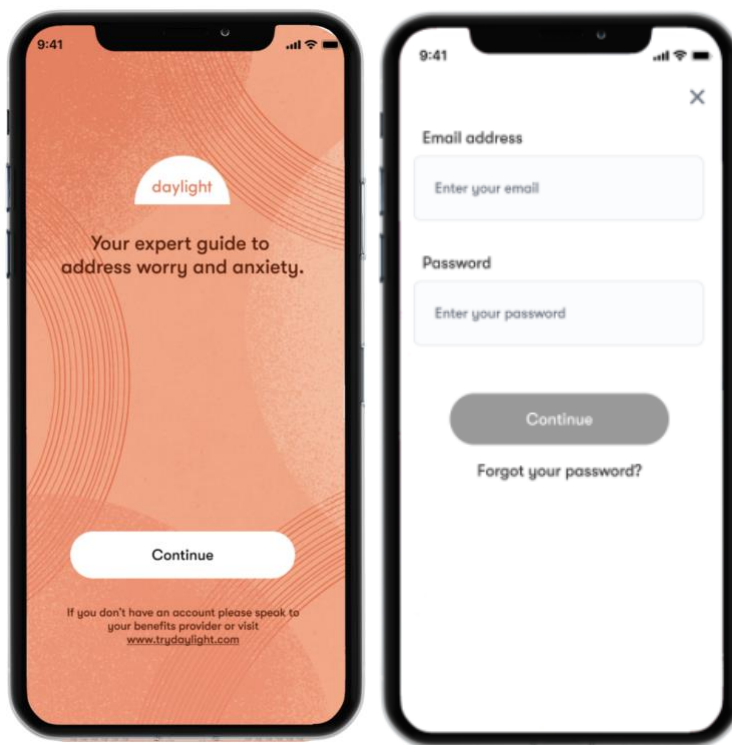

After you download the Daylight app from the Apple Store or Google Play Store you will be asked to sign into your account upon opening.

Let's Get Started

Once you login to the Daylight app, you will have access to the first session, "Let's Get Started" on the "Today" screen. Tap the play button to start the session, and answer all the questions to personalise the programme. Your first technique will then be offered on the "Today" screen.

To receive text message reminders from Daylight, provide your mobile number at the end of "Let's Get Started".
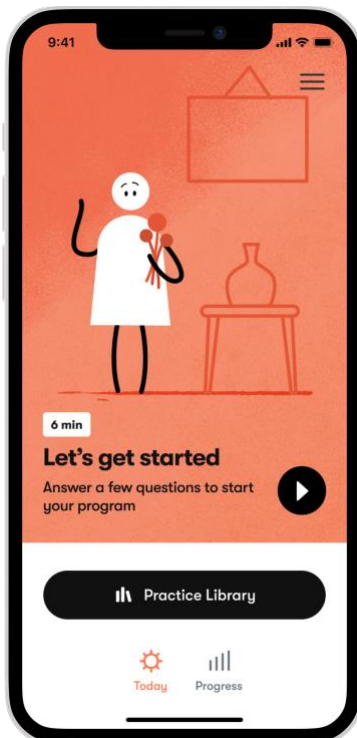
After tapping the play button on the "Let's Get Started" screen, you will be asked a series of questions that will help personalize your experience.

Pause and Resume Your Session

You can pause your session at any time by pressing the "Pause" button or by exiting the Session. Resume the session by pressing "Play". If a session is not completed within 2 hours, the contents will reset, and you will have to start again from the beginning.


You can pause your session by tapping on the pause icon on the bottom of the screen. If the pause button is not visible, tap anywhere on the screen to view it. To resume your session tap the play button.

Accessing Techniques

Techniques are 5-10 minutes long and consist of explanation videos, question prompts and guided exercises.

As you complete each technique, new techniques are offered to you through the "Today" screen until you have completed all the techniques in your programme. Be sure to complete the whole session, or you may not be offered new techniques.
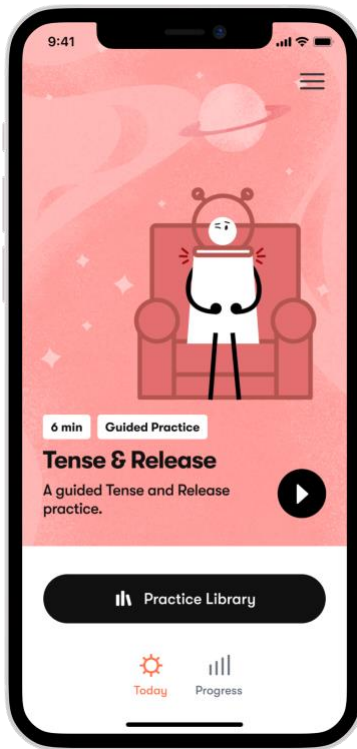

Techniques will populate your "Today" screen as you complete them.

Starting the Next Session

The "Today" screen will prompt you to start your next session, or you can visit the "Practice Library" to access a previous technique. After you learn all the techniques, you will see a short video guiding you on the next steps, and then will be able to continue to access practices through the "Practice Library".

Replay or Practice Techniques

You may replay or practice a technique at any time. Tap on "Practice Library" to view all available techniques and select play to start.
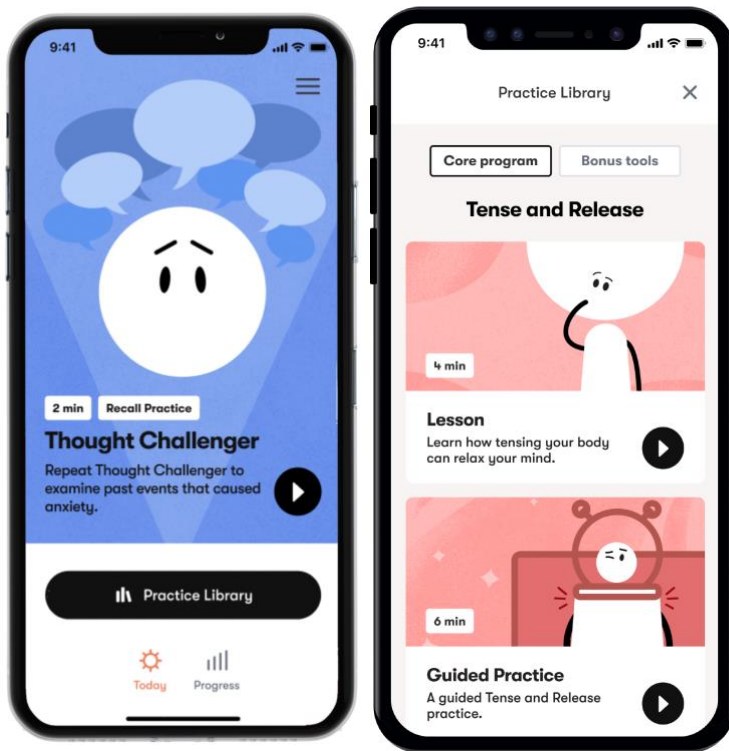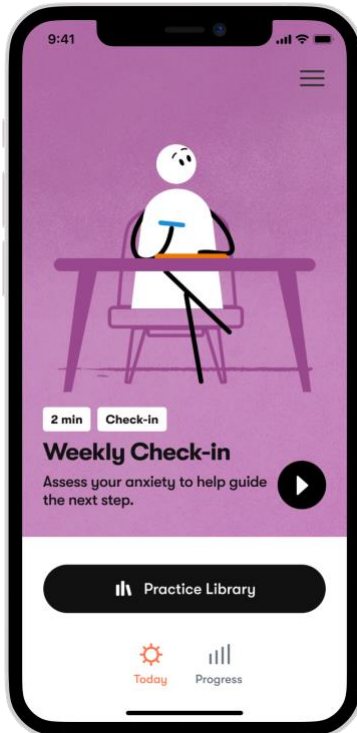

When you complete a technique, it will appear in the "Practice Library" so that you can revisit it.

Check-in Prompts

Seven days after you complete "Let's Get Started", your first "Check-in" prompt will appear. Answer the questions in the "Check-in" to track your progress and receive personalised recommendations for you, based on your feedback.

Your first "Check-in" prompt will appear seven days after completing the "Let's Get Started"
questionnaire.

Multi-Factor Authentication

Daylight provides you an option to enable Multi-Factor Authentication (MFA) to make the app
more secure. You will have the choice to verify your identity with SMS or an authenticator app.
However, note if you lose access to MFA after first enabling it, the Daylight team will not be able
restore your access to MFA and you will lose your progress in the Daylight program and will
have to start all over again at the beginning of the program.

What is Multi-Factor Authentication (MFA)?

MFA is an authentication method that requires the user to provide two or more verification
factors to gain access to a resource such as an application or an online account.

Why do I need MFA?

MFA protected services provide you with better security for your account by giving you more control over who can access it.

What options does Big Health support for MFA?

We support Authenticator apps such as Authy and Google Authenticator that pair with your account, then continually generate codes on a short timer which act as the needed verification key.

How do I enable MFA?

Before starting, be sure to download an authenticator app of your preference from the App Store or Google Play. Authy and Google Authenticator are popular choices.

1. Go to the "Account Settings" page in the Sleepio web or mobile application.
2. Turn on the "Multi-factor Authentication" toggle
3. Read the brief overview on the subsequent screen and then click "Continue"
4. Follow instructions on the next screen -
   - Open your Authenticator app
   - Add your Big Health account in the authenticator app
   - Pair your Big Health account with the authenticator app by:
     - Option 1 (web and mobile apps): Copying and pasting the key provided by Sleepio into your authenticator app
     - Option 2 (web only): Scanning the QR code displayed on screen using your authenticator app
   - Click "Continue"

5. Once your Big Health account has been added to the authenticator app, copy the 6-digit verification code provided by the authenticator app to Sleepio.

6. Click "Continue" to finish setting up MFA for your account.

What if I set up MFA and then happen to lose my phone or want to disable MFA?

Please email us for technical support at hello+mfa@bighealth.com.

Getting Support to Use Daylight

If you have a question about how to use Daylight, please email our support team at hello@trydaylight.com. We are here to help!

Compatible Devices

You can access Daylight on mobile devices running Android (v12 or higher) or iOS (v15 or higher). Supported web browsers for signing up to access Daylight include Chrome, Safari, and MS Edge. Daylight mobile app has been tested on iPhone X, 12 and 12 mini and on Android Motorola Z, LG G8 ThinQ, Samsung Galaxy S20 FE and Google Pixel 6 PRO.

Clinical Research

DeLTA-GAD Pivotal Study

Study design

A randomised controlled trial in adults with moderate to severe symptoms of Generalised Anxiety Disorder (GAD). 256 adults (18+) were randomly assigned to Daylight (n=128) or waitlist control (n=128).

Objectives

To examine the effect of Daylight on anxiety (7-item Generalised Anxiety Disorder scale [GAD-7]) at 6-weeks post-intervention (primary endpoint). Secondary outcomes included worry (Penn State Worry Questionnaire [PSWQ]), depressive symptoms (9-item Patient Health Questionnaire [PHQ-9]), sleep difficulty (Sleep Condition Indicator [SCI-8]), wellbeing (Warwick Edinburgh Mental Wellbeing Scale [WEMWBS]) and participant-specific quality of life (Patient-Generated Index) at post-intervention, and to examine effects on all outcomes at 10-weeks (controlled) and 6-month (uncontrolled) follow-ups.

Results

Daylight led to significant improvements in anxiety (GAD-7) at 6-weeks post intervention (d=1.08, p<0.001) compared to control, which was maintained at 10-weeks (d=1.43, p<0.001) and 6-month follow-up (p<0.001). Significant improvements were also found for worry (d=0.73, p<0.001), depressive symptoms (d=0.51, p<0.001), sleep difficulty (d=0.51, p=0.002), and wellbeing (d=0.64, p<0.001) compared to control at 6-weeks post-intervention. Outcomes continued to improve at 10-weeks follow-up. Significant improvements were also observed for Daylight participants' first most important area for concern (participant-specific quality of life) (d=0.34, p=0.010) at 6-weeks post-intervention. At 6-weeks post-intervention, significantly more participants in the Daylight group experienced GAD remission [65/107 (61%)] than those in the control group [38/122 (31%)] (p<0.001). At 10-weeks follow-up this increased to 71% (73/103) in the Daylight group compared to 33% (41/124) in the waitlist control group (p<0.001). The effects

of Daylight did not differ between demographic groups or those with more severe symptoms at baseline.
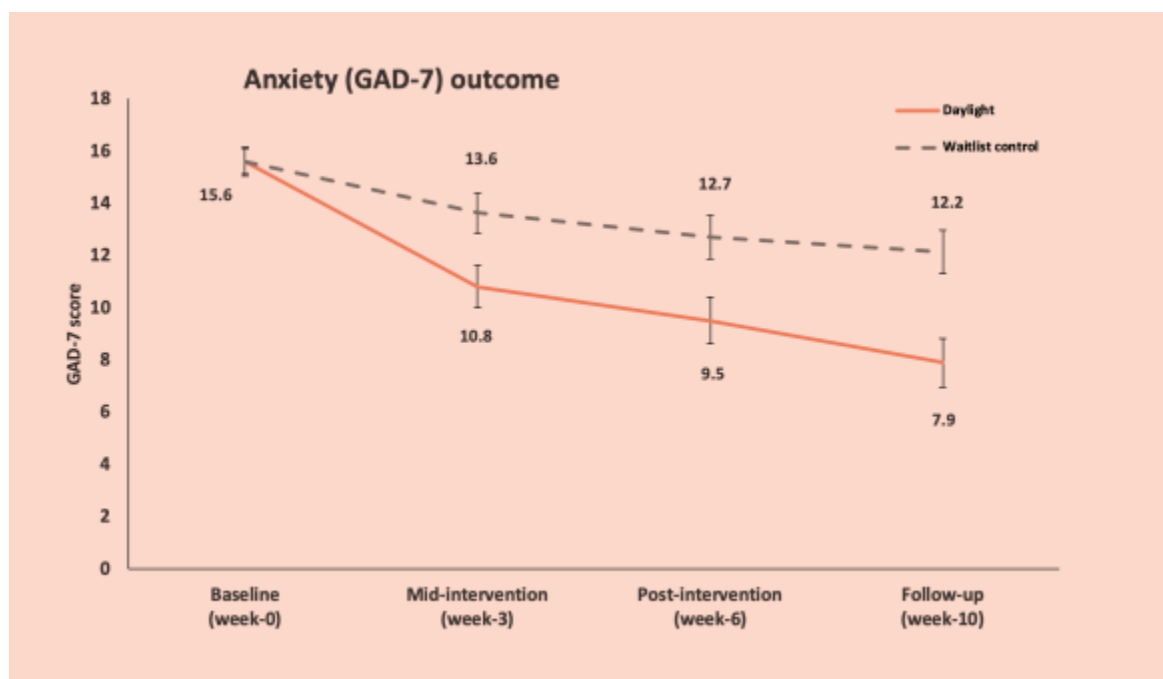
Outcomes from the DeLTA-GAD Pivotal Study

Safety and Compliance

One minor adverse event was reported concerning a participant who was frustrated by difficulties downloading and installing Daylight. No serious adverse events were reported. Participants receiving Daylight reported significantly fewer occurrences of unwanted symptoms than the control group during the 6-week study period including low mood, fatigue and/or exhaustion, extreme sleepiness, feeling agitated, difficulty remembering things, headache and/or migraine, difficulty concentrating and focusing on things, reduced motivation and/or energy, blurred vision, dizziness and feeling irritable ($p < 0.001$).

Reference

Carl, J.R., Miller, C.B., Henry, A.L., Davis, M.L., Stott, R., Smits, J.A.J., Emsley, R., Gu, J., Shin, O., Otto, M.W., Craske, M.G., Saunders, K.E.A., Goodwin, G.M., & Espie, C.A. (2020). Efficacy of digital Cognitive Behavioral Therapy for moderate-to-severe symptoms of Generalized Anxiety Disorder: A randomized controlled trial. *Depression and Anxiety*.

Daylight Proof of Concept Study

Study design

In a proof of concept, multiple-baseline single-case experimental design (SCED) study, 21 adults (18+) with moderate to severe symptoms of Generalised Anxiety Disorder (GAD) were randomised to one of three baseline durations (2-, 4-, or 6- weeks) and then received access to Daylight.

Objectives

To examine the feasibility of Daylight in terms of retention, safety, adherence and acceptability, and preliminary efficacy to reduce daily anxiety (assessed using a single item) and weekly anxiety (7-item Generalised Anxiety Disorder scale [GAD-7]) at 6-weeks post-intervention (primary endpoint). Secondary outcomes included weekly sleep (7-item Sleep Condition Indicator [SCI-7]), depressive symptoms (9-item Patient Health Questionnaire [PHQ-9]). Anxiety (GAD-7), depressive symptoms (PHQ-9), sleep (SCI-8), worry (Penn State Worry Questionnaire [PSWQ]), wellbeing (Warwick Edinburgh Mental Wellbeing Scale [WEMWBS]) CBT skills acquisition (Cognitive Behavioral Skills Questionnaire [CBTSQ]), work productivity (Work Productivity and Activity Impairment Index [WPAI]) and participant quality of life (Patient Generated Index) were also assessed at baseline, at post-intervention and follow-up.

Results

Participants found Daylight to be acceptable (76% (16/21) of participants completing all four modules, and 100% completing at least one), and were satisfied with the intervention (Mean=6.20, standard deviation=1.99, range=2-10, n=20), indicating good feasibility of Daylight. Daylight led to significant improvements in daily measures of anxiety (single-item; $p<0.001$). Significant decreases in weekly measures of anxiety (GAD-7) were examined from baseline to intervention phase ($p=0.024$) and baseline to follow-up ($p=0.017$). Significant improvements were also observed in weekly measures of depressive symptoms (PHQ-9) and sleep (SCI-7). There was a significant reduction in anxiety symptoms, depressive symptoms and sleep difficulty from initial assessment to post-intervention and from initial assessment to follow-up (all $p<0.001$). Significant improvements were similarly observed over time for worry (PSWQ), wellbeing (WEMWBS) and CBT skills (CBTSQ) (all $p<0.001$). There was also a significant improvement in participant quality of life over time ($p<0.001$-0.034). No significant improvements were observed in workplace outcomes (WPAI). Overall, 70% of participants no longer had clinically significant symptoms of anxiety (GAD), 61% no longer had significant depressive symptoms, and 40% no longer had significant sleep difficulty at post-intervention.
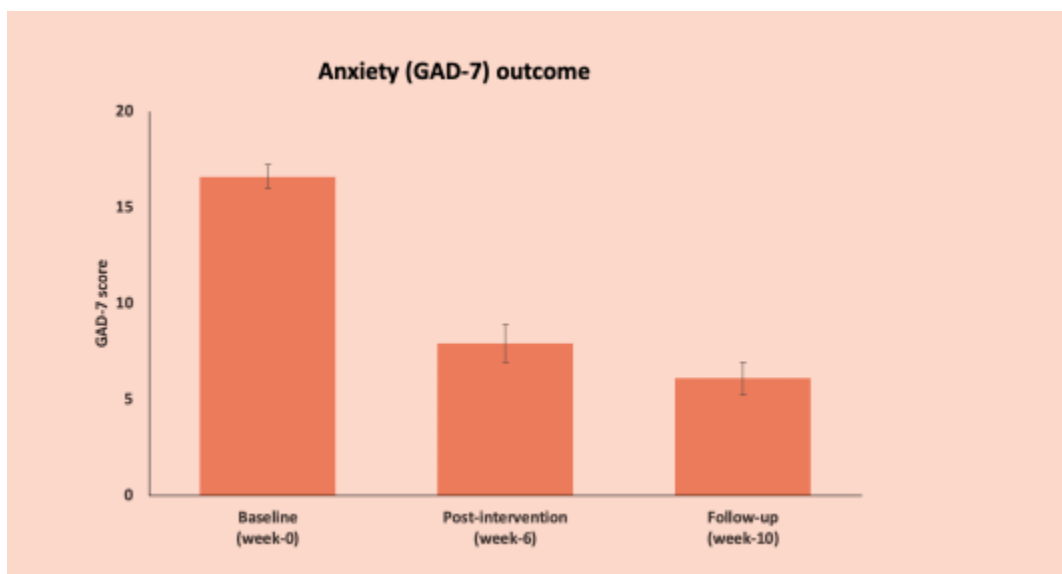
Outcomes from the Daylight Proof of Concept Study

Safety and Compliance

No adverse events were reported by participants. Nine of the 21 participants (43%) reported unwanted symptoms including agitation, low mood, fatigue/exhaustion and reduced motivation and/or lethargy.

Reference

Miller, et al. (2021). Feasibility and efficacy of a digital CBT intervention for symptoms of worry and anxiety: A randomized multiple-baseline study. *Journal of Behavior Therapy and Experimental Psychiatry, 70,* 101609

Symbols Glossary

	Caution, be aware of safety information to order to avoid undesirable consequences
	Read Instructions for Use
	Manufacturer

Big Health

Manufacturer

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