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Utilising an app-based behavioural intervention to increase the light exposure of office workers: A pilot randomised controlled trial

Submission date 12/07/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/07/2021	**Overall study status** Completed	
Last Edited 07/12/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This study aims to test a behavioural intervention designed to increase the daytime light exposure of office workers. As this is a pilot trial, the researchers are primarily interested in how feasible and acceptable the study design/procedures and intervention are.

Who can participate?
Healthy office workers who are working and living within the Oxford Ring Road, full-time, in August/September/October/November/December of this year (2021), are aged 25-45 years, are an Android/iOS smartphone user (with a consistent internet connection indoors and outdoors) and are able to read and understand English.

What does this study involve?
Participants will be sent an envelope containing an actigraph device and instructions about the study, including how to download the study app. This envelope will be sent to their home address. Participants will need to download the OxTrack app from the Google Play Store or Apple App Store. For the duration of the study (4 weeks), participants will need to wear the actigraph device on their non-dominant wrist. Participants will also need to complete daily surveys in the OxTrack app for the duration of the 4 weeks: 'My Sleep' (when they get out of bed), 'My Day' (just before bed) and 'My Mood' (between 8pm and 9pm). Furthermore, participants will be asked to complete three other surveys at the start of week 1, end of week 2 and the end of week 4. At the end of week 4, participants will be asked to complete one additional survey. At the end of week 2 participants will also be asked to read a poster. For weeks 3 and 4 participants will be asked to keep an eye out for "click me" notifications. Participants will complete the study whilst continuing their normal day-to-day activities. Once the study is complete, participants will be asked to return the actigraph device in a pre-paid envelope.

What are the possible benefits and risks of participating?
Participants will be paid £100 for their participation. The questionnaires and data collected by the sensors are minimally intrusive. Throughout the study participants will be asked to report on their emotional state, which could cause distress.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
February 2021 to December 2021

Who is funding the study?
1. SLL (UK)
2. Department of Experimental Psychology, University of Oxford (UK)
3. St Catherine's College, University of Oxford (UK)
4. University of Oxford Medical Sciences Internal Fund (UK)
5. Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MS IDREC R75745

Study information

Scientific Title
Utilising an app-based ‘nudge’ behavioural intervention to increase the light exposure of office workers: A double-blind, parallel group, matched-pairs, randomised placebo-controlled superiority pilot trial

Acronym
OxTrack

Study objectives
Current study hypothesis as of 08/03/2022:
The primary objectives for this study focus on assessing the feasibility and acceptability of the intervention and trial procedures.

Feasibility:
1. To assess the mean percentage of nudge notifications read by participants
2. To assess the percentage of participants that pass the Light Quiz
3. To assess how many prospective participants complete the screening survey
4. To assess what percentage of prospective participants are eligible to participate in the study
5. To assess what percentage of eligible prospective participants consent to data collection after screening
6. To assess what percentage of eligible participants are successfully matched in a pair
7. To assess what percentage of participants drop out/are lost to follow up
8. To qualitatively assess why participants did not consent to data collection/why they dropped out of the study
9. To assess the percentage of participants who were blind to their group allocation
10. To assess whether the blinding of researchers in the study was successful
11. To assess the percentage of contamination in the study
12. To assess what percentage of participants engaged in co-intervention
13. To assess the mean percentage of daily questionnaires completed with valid data
14. To assess the mean percentage of repeat questionnaires completed with valid data
15. To assess the average percentage of actigraphs worn with valid data

Acceptability:
1. To assess the acceptability of the nudge intervention using the Theoretical Framework of Acceptability (TFA)
2. To assess the acceptability of the placebo nudge using the TFA
3. To assess the acceptability of the study procedures using the TFA
4. To qualitatively assess the barriers and facilitators participants experienced when attempting to/carrying out the behaviours.
5. To assess what percentage of participants provide valid secondary outcome data

Sample size calculation:
1. To carry out a sample size calculation for a future definitive main trial

Previous study hypothesis:
The primary objectives for this study focus on assessing the feasibility and acceptability of the intervention and trial procedures.

Feasibility:
1. To assess the average percentage of nudge notifications read by participants
2. To assess the percentage of participants that pass a domain-specific quiz
3. To assess how many prospective participants complete the screening survey
4. To assess what percentage of prospective participants are eligible to participate in the study
5. To assess what percentage of eligible prospective participants consent to data collection after screening
6. To assess what percentage of eligible participants are successfully matched in a pair
7. To assess what percentage of participants drop out/are lost to follow up
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13. To assess the average percentage of daily questionnaires completed with valid data
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15. To assess the average percentage of actigraphs worn with valid data

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5. To assess what percentage of participants provide valid secondary outcome data

Sample size calculation:
1. To carry out a sample size calculation for a future definitive main trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 07/10/2021:
Approved 06/05/2021, first amendment approved 19/07/2021, second amendment approved 20/08/2021, third amendment approved 14/09/2021, University of Oxford Medical Sciences Interdivisional Research Ethics Committee (Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD, UK; +44 (0)1865 616577; ethics@medsci.ox.ac.uk), ref: R75745/R001, first amendment ref: R75745/R002, second amendment ref: R75745/R003, third amendment ref: R75745/R004

Previous ethics approval:
Approved 06/05/2021, University of Oxford Medical Sciences Interdivisional Research Ethics

Committee (Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD, UK; +44 (0)1865 616577; ethics@medsci.ox.ac.uk), ref: R75745/R001; amendment approved 19/07/2021 (R75745/R002)

Study design
Single-centre interventional double-blind parallel-group matched-pairs randomized placebo-controlled superiority pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Improving the light exposure of office workers

Interventions
Current intervention as of 08/03/2022:
Randomisation/allocation: sequence generation
The researchers will perform the assignment of individuals to treatment groups and the allocation of groups to intervention and placebo independently. First, using an optimal non-bipartite matching and matched randomization algorithm (Lu, Greevy, Xu, & Beck, 2012) (Greevy, et al., 2012) the researchers will create matched pairs based on age, gender and PSQI score. Second, using a true random number generator (sampling atmospheric noise), they will then assign group 1 and 2 arising from the matching to be either intervention or placebo on a 1:1 basis. Sequences will be generated randomly by using a computerised coin flip. The algorithm will choose the order of participants and the researchers will truncate after n places.

Allocation: concealment
Researcher 2 will recruit participants and score their online screening questionnaires. Researcher 2 will be the only individual with access to the screening data. The ID, age, gender, and PSQI score of prospective participants who screen into the study and have agreed to take part in data collection, will be passed onto Researcher 1. Researcher 1 will act as the equivalent of a central randomised service, matching participants into pairs and randomly allocating individuals within those pairs to either the intervention or placebo group. Researcher 1 will have no contact with the participants and will not be involved with recruitment, screening, or data collection. Allocation concealment will be achieved as Researcher 2 who will be enrolling participants will not be able to anticipate which groups participants will be allocated to. Participants will be unaware of the allocation sequence.

Educational poster
For the nudges to act as reminders, participants will first have to be educated on how they can increase their daytime light exposure and why it is important for their health to do so. To this effect, the researchers have designed an educational poster that will be given to both groups (placebo and intervention) via a link sent by email on the last day of week 2. Participants will be asked not to save or download the poster.

Intervention
The researchers have designed 14 reminder nudges that will be delivered via the OxTrack app notifications to remind participants of the light exposure behaviours detailed in the educational poster. One nudge will be delivered to each individual in the experimental group, daily at 9 am BST from the start of week 3 to the end of week 4 (14 reminder nudges for 14 days). Participants will receive the notifications whilst going about their daily lives.

Placebo
The placebo will superficially take on the appearance of the active reminder nudges. There are 14 placebo reminder nudges, one for each day of the intervention period. The placebo reminder nudges will be sent via OxTrack notifications at 9 am BST.

Previous intervention as of 07/10/2021:
Randomisation/allocation: sequence generation
The researchers will perform the assignment of individuals to treatment groups and the allocation of groups to intervention and placebo independently. First, using an optimal non-bipartite matching and matched randomization algorithm (Lu, Greevy, Xu, & Beck, 2012) (Greevy, et al., 2012) the researchers will create matched pairs based on age, gender and PSQI score. Second, using a true random number generator (sampling atmospheric noise), they will then assign group 1 and 2 arising from the matching to be either intervention or placebo on a 1:1 basis. Sequences will be generated randomly by using a computerised coin flip. The algorithm will choose the order of participants and the researchers will truncate after n places.

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Educational poster
For the nudges to act as reminders, participants will first have to be educated on a domain-specific set of behaviours and why it is important for their health to do so. To this effect, the researchers have designed an educational poster that will be given to both groups (placebo and intervention) via a link sent by email on the last day of week 2. Participants will be asked not to save or download the poster.

Intervention
The researchers have designed 14 reminder nudges that will be delivered via the OxTrack app notifications to remind participants of the behaviours detailed in the educational poster. One

nudge will be delivered to each individual in the experimental group, daily at 9 am BST from the start of week 3 to the end of week 4 (14 reminder nudges for 14 days). Participants will receive the notifications whilst going about their daily lives.

Placebo
The placebo will superficially take on the appearance of the active reminder nudges. There are 14 placebo reminder nudges, one for each day of the intervention period. The placebo reminder nudges will be sent via OxTrack notifications at 9 am BST.

Previous interventions:
Randomisation/allocation: sequence generation
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Allocation: concealment
Researcher 2 will recruit participants and score their online screening questionnaires. Researcher 2 will be the only individual with access to the screening data. The age, gender and name of prospective participants who screen into the study and have agreed to take part in data collection will be passed onto Researcher 1. Researcher 1 will act as the equivalent of a central randomised service, matching participants into pairs and randomly allocating individuals within those pairs to either the intervention or placebo group. Researcher 1 will have no contact with the participants and will not be involved with recruitment, screening, or data collection. Allocation concealment will be achieved as Researcher 2 who will be enrolling participants will not be able to anticipate which groups participants will be allocated to. Participants will be unaware of the allocation sequence.

Educational poster
For the nudges to act as reminders, participants will first have to be educated on a domain-specific set of behaviours and why it is important for their health to do so. To this effect, the researchers have designed an educational poster that will be given to both groups (placebo and intervention) via a link sent by email on the last day of week 2. Participants will be asked not to save or download the poster.

Intervention
The researchers have designed 14 reminder nudges that will be delivered via the OxTrack app notifications to remind participants of the behaviours detailed in the educational poster. One nudge will be delivered to each individual in the experimental group, daily at 8 am BST from the start of week 3 to the end of week 4 (14 reminder nudges for 14 days). Participants will receive the notifications whilst going about their daily lives.

Placebo
The placebo will superficially take on the appearance of the active reminder nudges. There are 14 placebo reminder nudges, one for each day of the intervention period. The placebo reminder nudges will be sent via OxTrack notifications at 8 am BST.

Intervention Type

Behavioural

Primary outcome measure
Feasibility:
1. Feasibility of the intervention will be measured using an app and quiz and the feasibility section of the custom feasibility and acceptability questionnaire at the end of the trial
2. Feasibility of the design and procedures will be measured using a screening survey, custom allocation/randomisation script consent forms, a follow-up questionnaire, the feasibility section of the custom feasibility and acceptability questionnaire and a self-report question at the end of the trial
3. Feasibility of the design and procedures in terms of completeness will be assessed by calculating the average percentage of daily questionnaires completed with valid data (GoodBarber), the average percentage of repeat questionnaires completed with valid data (REDCap), and the average percentage of actigraphs worn with valid data at the end of the trial (added 20/07/2021)

Acceptability:
1. Acceptability of the intervention will be measured using the acceptability section of the custom feasibility and acceptability questionnaire at the end of the trial
2. Acceptability of the placebo will be measured using the acceptability section of the custom feasibility and acceptability questionnaire at the end of the trial
3. Acceptability of the study procedures will be measured using the acceptability section of the custom feasibility and acceptability questionnaire at the end of the trial

Sample size calculation:
1. Sample size for a definitive main trial calculated using a non-central t-distribution (NCT) approach at the end of the trial

Secondary outcome measures
Three secondary outcome domain-specific measures will be assessed

Overall study start date
12/02/2021

Completion date
20/12/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 08/03/2022:
1. Aged 25-45 years
2. Healthy
3. Office worker (work sitting at a desk indoors for the working day)
4. Living within the Oxford Ring Road, full-time (Monday-Sunday), in August/September/October/November/December 2021
5. Working within the Oxford Ring Road, full-time (“9-5”, Monday-Friday), in August/September/October/November/December 2021
6. Android/iOS smartphone user (with a consistent internet connection indoors and outdoors)
7. Able to read and understand English

Previous participant inclusion criteria as of 07/10/2021:
1. Aged 25-45 years
2. Healthy
3. Office worker (work sitting at a desk indoors for the working day)
4. Living within the Oxford Ring Road, full-time (Monday-Sunday), in August/September/October /November 2021
5. Working within the Oxford Ring Road, full-time ("9-5", Monday-Friday), in August/September /October/November 2021
6. Smartphone user (with a consistent internet connection indoors and outdoors)
7. Able to read and understand English

Previous participant inclusion criteria:
1. Aged 25-45 years
2. Healthy
3. Office worker (work sitting at a desk indoors for working day)
4. Living within the Oxford Ring Road, full-time (Monday-Sunday), in August/September 2021
5. Working within the Oxford Ring Road, full-time ("9-5", Monday-Friday), in August/September 2021
6. Working from home, full-time ("9-5", Monday-Friday), in August/September 2021
7. Android smartphone user (with a consistent internet connection indoors and outdoors)
8. Able to read and understand English

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
44

Key exclusion criteria
Current participant exclusion criteria as of 08/03/2022:
1. Generalized Anxiety Disorder, Panic Disorder, Social Anxiety Disorder, PTSD (GAD-7; ≥10)
2. Major Depression (PHQ-9; ≥10)
3. Suicidal ideation with intent or attempted suicide within past 2 months
4. Formal diagnosis of a mental health disorder
5. Extreme early and late chronotypes (μMCTQ; ≤2 or ≥6)
6. Shift or night worker in the past 3 months
7. Formal diagnosis of a sleep disorder
8. Drug abuse (DAST-10; ≥3)
9. Alcohol use disorder (AUDIT; ≥16)
10. Caffeine dependence (SDS; ≥4)
11. Sleep medication
12. Smoker/vape user
13. Antidepressants (e.g., serotonin reuptake inhibitors)
14. Anxiety medication
15. Photosensitive medication

16. Benzodiazepines or non-benzodiazepine hypnotics
17. Beta/alpha blockers
18. Underweight and obese BMI (less than 18.5 or greater than 29.9 kg/m²)
19. Significant medical or surgical condition
20. Planning major surgery in the next 6 months
21. Significant pain or physical distress
22. Serious head injury in the past year
23. Neurological disorder
24. Neurodevelopmental disorder
25. Physical disability preventing moderate exercise (e.g., going for a 30-min walk)
26. Eye disease
27. Life expectancy <1 year
28. Menopausal
29. Lactating or pregnant
30. Significant recent, or foreseeable life events (death in family, moving to a new house, divorce)
31. Undergone light therapy in the last month/plan to have light therapy within the next 6 months
32. Received/receiving psychological treatment for a sleep disorder
33. Currently taking part in a study involving a drug or behavioural intervention/ will be taking part in such a study in the next 3 months
34. Knowing of someone who is participating/has participated in the data collection aspect of this study

Previous participant exclusion criteria as of 07/10/2021:
1. Generalized Anxiety Disorder, Panic Disorder, Social Anxiety Disorder, PTSD (GAD-7; ≥10)
2. Major Depression (PHQ-9; ≥10)
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9. Alcohol use disorder (AUDIT; ≥16)
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17. Beta/alpha blockers
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20. Planning major surgery in the next 6 months
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26. Eye disease
27. Life expectancy <1 year

28. Menopausal
29. Lactating or pregnant
30. Significant recent, or foreseeable life events (death in family, moving to a new house, divorce)
31. Undergone domain-specific therapy in the last month/plan to have domain-specific therapy within the next 6 months
32. Received/receiving psychological treatment for a sleep disorder
33. Currently taking part in a study involving a drug or behavioural intervention/ will be taking part in such a study in the next 3 months
34. Knowing of someone who is participating/has participated in the data collection aspect of this study

Previous participant exclusion criteria:
1. Generalized Anxiety Disorder, Panic Disorder, Social Anxiety Disorder, PTSD (GAD-7; ≥10)
2. Major Depression (PHQ-9; ≥10)
3. Suicidal ideation with intent or attempted suicide within past 2 months
4. Formal diagnosis of a mental health disorder
5. Poor sleepers (PSQI; >5)
6. Extreme early and late chronotypes (μMCTQ; ≤2 or ≥6)
7. Shift or night worker in the past 3 months
8. Formal diagnosis of a sleep disorder
9. Drug abuse (DAST-10; ≥3)
10. Alcohol use disorder (AUDIT; ≥8)
11. Caffeine dependence (SDS; ≥4)
12. Sleep medication
13. Smoker/vape user
14. Antidepressants (e.g., serotonin reuptake inhibitors)
15. Anxiety medication
16. Photosensitive medication
17. Benzodiazepines or non-benzodiazepine hypnotics
18. Beta/alpha blockers
19. Underweight and obese BMI (less than 18.5 or greater than 29.9 kg/m^2)
20. Significant medical or surgical condition
21. Planning major surgery in the next 6 months
22. Significant pain or physical distress
23. Serious head injury in the past year
24. Neurological disorder
25. Neurodevelopmental disorder
26. Physical disability preventing moderate exercise (e.g., going for a 30-min walk)
27. Eye disease
28. Life expectancy <1 year
29. Menopausal
30. Lactating or pregnant
31. Significant recent, or foreseeable life events (death in family, moving to a new house, divorce)
32. Undergone domain-specific therapy in the last month/plan to have domain-specific therapy within the next 6 months
33. Tracking your health using a device/app (Fitbit, sleep application, diet tracker, etc)
34. Received/receiving psychological treatment
35. Received/receiving psychological treatment for a sleep disorder
36. Currently taking part in a study involving a drug or behavioural intervention/ will be taking part in such a study in the next 3 months

37. Knowing of someone who is participating/has participated in the data collection aspect of this study

Date of first enrolment
17/07/2021

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Department of Experimental Psychology
Anna Watts Building
Radcliffe Observatory Quarter
Woodstock Rd
Oxford
United Kingdom
OX2 6GG

Sponsor information

Organisation
University of Oxford

Sponsor details
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+44 (0)1865 271444
enquiries@psy.ox.ac.uk

Sponsor type
University/education

Website
https://www.psy.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
SLL

Funder Name
St. Catherine's College, University of Oxford

Alternative Name(s)
St Catherine's College, University of Oxford, St Catherine’s College Oxford

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Department of Experimental Psychology, University of Oxford

Funder Name
University of Oxford Medical Sciences Internal Fund

Results and Publications

Publication and dissemination plan
This trial will be disseminated in several ways. Firstly, this protocol will be pre-registered on the Open Science Framework, with an embargo that will end with the study's completion. Secondly, this protocol will be written up and submitted for publication - the researchers aim to submit the protocol paper to a journal prior to data collection. Thirdly, this trial will be written up as a master's thesis. Fourthly, once the results of the study have been analysed in their entirety, a paper will be submitted for publication (the researchers anticipate it will take about 5 months from the end of data collection to submission). Results from this trial will be disseminated regardless of the magnitude or direction of effect.

Intention to publish date
31/10/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored on the Open Science Framework.

IPD sharing plan summary
Stored in repository