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Light and Ion Treatment to Enhance Medication Efficacy in Depression

Submission date	Recruitment status	[X] Prospectively registered
17/08/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00958204

Protocol serial number
MCT-94832; H09-01015

Study information

Scientific Title
A randomised controlled trial of light therapy, negative ion therapy and fluoxetine in non-seasonal major depression

Study objectives
This study will investigate the additional benefits of light and ion therapy as added treatments to an antidepressant (fluoxetine) in subjects with major depressive disorder (MDD) versus treatment with fluoxetine alone. Outcomes will include depressive symptom rating scales and measures of quality of life, work absence and productivity, and use of health care services. The primary hypotheses are that, in patients with non-seasonal MDD of at least moderate severity:
1. Bright light therapy or negative ion therapy will be superior to a placebo condition in reducing symptoms of depression, and
2. The combination of fluoxetine and bright light or negative ion therapy is more effective than either monotherapy condition

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of British Columbia: Clinical Research Ethics Board approved on the 5th June 2009 (ref: H09-01015)
2. Vancouver Coastal Health Authority: Vancouver Coastal Health Research Institute approved on the 17th June 2009 (ref: V09-0141)

Study design
Multicentre double-blind (subject and rater) randomised parallel-design trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Major depressive disorder

Interventions
1. Experimental: Light therapy/negative ion therapy (active) plus placebo pill
2. Experimental: Light therapy/negative ion therapy (active) plus fluoxetine 20 mg/day
3. Active Comparator: Light therapy/negative ion therapy (inactive) plus fluoxetine 20 mg/day
4. Placebo Comparator: Light therapy/negative ion therapy (inactive) plus placebo pill

Negative ion therapy: Ion generator emitting 4.5 x 10^14 ions/second for 30 minutes daily in the morning
Light therapy: 10,000 lux fluorescent light box for 30 minutes daily in the morning.

Note: Half of all devices used (light boxes and negative ion generators) will be inactive (placebo condition). Duration of treatment and follow-up: 8 weeks.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Fluoxetine

Primary outcome(s)
Change in adjusted HAM-D scores at 2-month follow-up

Key secondary outcome(s)
At 2-month follow-up:
1. Clinical response and remission rates
2. Absenteeism and work productivity
3. Adverse events
4. Quality of life
5. Health services

Completion date
01/03/2013

Eligibility

Key inclusion criteria
1. Male and female outpatients aged 19 - 60 years
2. Patients will meet Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for major depressive disorder as determined by the mood disorders section of the Mini International Neuropsychiatric Interview (MINI)
3. A score of 20 or greater on the Hamilton Depression Rating Scale (Ham-D), indicating at least moderately severe depression
4. Competency to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnant women, lactating women and sexually active women of childbearing potential who are not using medically accepted means of contraception
2. Serious suicidal risks as judged by the clinician and the MINI
3. The following DSM-IV diagnoses (to ensure a homogeneous diagnostic group): organic mental disorders; substance abuse/dependence, including alcohol, active within the last year; schizophrenia, paranoid, or delusional disorders; other psychotic disorders; panic disorder or generalised anxiety disorder, if a primary diagnosis; obsessive-compulsive disorder or post-traumatic stress disorder; bipolar disorder; bulimia nervosa or anorexia nervosa
4. Serious illness including cardiac, hepatic, renal, respiratory, endocrinologic, neurologic and

haematologic disease that is not stabilised, or a past history of convulsions
5. Any retinal disease or systemic illness with active retinal involvement (e.g. diabetes) that precludes the use of bright light
6. Patients who have a history of severe allergies and multiple drug adverse reactions
7. Regular or current use of other psychotropic drugs, including lithium and tryptophan
8. Patients treated with beta blocking drugs
9. Hypertensive patients being treated with guanethidine, reserpine, clonidine or methyldopa (because of possible mood-altering effects of those drugs)
10. Use of monoamine oxidase inhibitors within 14 days of Visit 1 (to ensure no drug interactions between fluoxetine and MAOIs), or use of heterocyclic antidepressants within 7 days of Visit 1 (to ensure adequate washout period of two weeks between stopping previous drug and start of treatment at Visit 2)
11. Previous use of fluoxetine or light therapy
12. Treatment resistance in the current episode, as defined by failure (lack of clinically significant response) of two or more antidepressants given at therapeutic doses for at least 6 weeks
13. Patients who start formal psychotherapy (e.g. cognitive-behavioural or interpersonal psychotherapy) within 3 months of Visit 1, or who plan to initiate such psychotherapy during this study
14. Patients involved in any other form of treatment for depression

Date of first enrolment
01/09/2009

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
Canada

Study participating centre
2C7 - 2255 Wesbrook Mall
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Sponsor information

Organisation
University of British Columbia (Canada)

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-94832)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016	29/01/2019	Yes	No
Results article	results	24/07/2018	29/01/2019	Yes	No