

# Light and Ion Treatment to Enhance Medication Efficacy in Depression

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
17/08/2009	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
20/08/2009	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> 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

### Contact name

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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  $4.5 \times 10^{14}$  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**

Vancouver

Canada

V6T 2A1

## **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?
<a href="#">Results article</a>	results	01/01/2016	29/01/2019	Yes	No
<a href="#">Results article</a>	results	24/07/2018	29/01/2019	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes