

Learning to live better with lupus: the Health Improvement and Prevention Program (HIPP) in systemic lupus erythematosus

Submission date 16/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/02/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00188357

Protocol serial number

MCT-82939

Study information

Scientific Title

The Health Improvement and Prevention Program (HIPP) in systemic lupus erythematosus: a randomised, cross-over, open-label efficacy study

Acronym

HIPP

Study objectives

1. The Health Improvement and Prevention Program (HIPP) will improve the physical component (PCS) and mental component (MCS) summary scores of the 36-item short form (SF-36) health status survey by an average of 4 points
2. HIPP will reduce the Framingham 8-year projected risk of cardiovascular disease (CVD) in persons with systemic lupus erythematosus (SLE) by 20%
3. HIPP will improve the flow mediated dilatation (FMD) of brachial arteries significantly

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Research Ethics Board of the University Health Network, Toronto approved on the 13th January 2004 (ref: 03-0605-A)
2. Research Ethics Board of McGill University approved on the 1st December 2006 (ref: 03-034)
3. Research Ethics Board of the University of Western Ontario approved on the 31st January 2008 (ref: 13732)

Study design

Randomised, cross-over, open-label efficacy study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Systemic lupus erythematosus

Interventions

Experimental interventions:

1. Non-drug coronary artery risk reduction in the setting of lupus measured at three months for one year followed by every six months for one year
2. Non-drug osteoporosis risk reduction in the setting of lupus measured at three months for one year followed by every six months for one year
3. Non-drug exercise in the setting of lupus measured at three months for one year followed by every six months for one year
4. Non-drug mindfulness based stress reduction in the setting of lupus measured at three months for one year followed by every six months for one year

Control intervention:
Usual care for 12 months.

Added 26/02/2009:

Secondary sponsor details:
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Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

36-item short form health survey physical and mental component summary scale (SF-36 PCS and MCS) scores, coronary disease risk reduction profiles and flow-mediated dilatation of the brachial artery yearly for two years.

Key secondary outcome(s)

1. Bone health improvement: yearly while on prednisone; every two years for all others
2. Adherence to treatment: every three months for one year and every six months for one year

Completion date

01/12/2010

Eligibility

Key inclusion criteria

1. Systemic lupus erythematosus according to American College of Rheumatology (ACR) criteria
2. 18 years or older

3. Female
4. Able to read and English or French

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. History of angina
2. Myocardial infarct
3. Cerebral vascular accident
4. Trans-ischaemic attack
5. Peripheral vascular disease
6. Osteoporosis with fracture confirmed by radiology
7. Pregnant or planning within two years
8. Cancer (if cancer-free for five years then eligible)

Date of first enrolment

01/08/2003

Date of final enrolment

01/12/2010

Locations**Countries of recruitment**

Canada

Study participating centre

UHN - TWH Research Institute

Toronto, Ontario

Canada

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Sponsor information

Organisation

University Health Network (Canada)

ROR

<https://ror.org/042xt5161>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-82939)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes