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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	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 16/06/2008	**Overall study status** Completed	
Last Edited 19/02/2019	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul R. Fortin

Contact details
UHN - TWH Research Institute
Toronto Western Hospital, MP10-304
399 Bathurst Street
Toronto, Ontario
Canada
M5T 2S8
+1 416 603 6265
pfortin@uhnresearch.ca

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:
Toronto Western Hospital (Canada)
c/o Dr. Paul Fortin
University Health Network
399 Bathurst Street
MP-10-304
Toronto, Ontario, M5T-2S8
Canada
Tel: +1 416 603 5800 ext. 6267
Fax: +1 416 603 6288
Email: pfortin@uhnresearch.ca

Contact for public queries:
Dr Ellie Aghdassi, Ph.D.
University Health Network
Toronto Western Hospital
399 Bathurst Street
MP-10-301
Toronto, Ontario, M5T-2S8
Canada
Tel: +1 416 603 5800 ext. 2822
Fax: +1 416 603 6288
Email: ellie.aghdassi@uhn.on.ca

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
M5T 2S8

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