# Pan African Clinical Trials Registry

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|---|---|---|---|
| **Trial no.:** | PACTR201405000823418 | **Date registered:** | 2014/05/08 |
| **Trial Status:** | **Retrospective registration - this trial was registered after enrolment of the first participant** | | |

## TRIAL DESCRIPTION

| | |
|---|---|
| **Public title** | Whole Body Vibration in Rheumatoid Arthritis |
| **Official scientific title** | Whole Body Vibration in Rheumatoid Arthritis |
| **Brief summary describing the background and objectives of the trial** | Background: Rheumatoid arthritis (RA) is a chronic autoimmune condition that results in pain and disability. Patients with RA are may be forced into a sedentary lifestyle and, as such, often become predisposed to poor bone health. Patients with RA may also experience a decreased health related quality of life (HRQoL) due to their disease. Whole body vibration (WBV) is a form of exercise that stimulates bone loading through forced oscillation. WBV has also been shown to decrease pain and fatigue in other rheumatic diseases, as well as to increase muscle strength. This paper reports on the development of a semi randomised controlled clinical trial to assess the impact of a WBV intervention aiming to attenuate bone loss, improve functional ability and habitual physical activity levels in patients with RA. Methods and Design: This study is a controlled clinical trial consisting of a cohort of patients with established RA assigned to either a WBV group or a CON (control) group. Patients in the WBV group will undergo three months of twice weekly intermittent WBV sessions, while the CON group will receive standard care and continue with normal daily activities. All patients will be assessed at baseline, following the three month intervention, and six months post intervention. Main outcomes will be an attenuation of loss of bone mineral density (BMD) at the hip and changes in RA disease activity, HRQoL, habitual physical activity levels and body composition. Discussion: This study will provide important information regarding the effects of WBV on BMD in patients with RA, as well as novel data regarding the potential changes in objective habitual physical activity patterns that may occur following the intervention. The sustainability of the intervention will also be assessed. |
| **Type of trial** | CCT |
| **Acronym (If the trial has an acronym then please provide)** | |
| **Disease(s) or condition(s) being studied** | Rheumatoid arthritis, osteoporosis |
| **Purpose of the trial** | Treatment |
| **Anticipated trial start date** | 2013-08-01 |
| **Actual trial start date** | 2013-08-01 |
| **Anticipated date of last follow up** | 2014-02-20 |
| **Actual date of last follow up** | 2014-02-20 |
| **Anticipated target sample size (number of participants)** | 32 |
| **Actual target sample size (number of participants)** | 31 |
| **Recruitment status** | Closed to recruitment: follow up complete |
| **Publication URL** | |

| Secondary Ids | Issuing authority/Trial register | Links to Secondary ID |
|---|---|---|

## STUDY DESIGN

| Intervention assignment | Allocation to intervention | If randomised, describe how the allocation sequence was generated | Describe how the allocation sequence/code was concealed from the person allocating the participants to the intervention arms | Masking | If masking / blinding was used |
|---|---|---|---|---|---|
| Parallel: different groups receive different interventions at same time during study | Non-randomised | | Numbered allocation | Masking/blinding used | Care giver/Provider, |

## INTERVENTIONS

| Intervention type | Intervention name | Dose | Duration | Intervention description | Group size | Nature of control |
|---|---|---|---|---|---|---|
| Experimental group | Whole body vibration (WBV) | twice per week | 12 weeks | Vibration training will consist of 24 total sessions (performed twice weekly for 12 weeks); in intermittent bouts of 60 seconds on the plate and 30 seconds off the plate, repeated 10 times (this protocol was designed to stimulate greater osteogenic responses due to the constant stimulus to the mechanoreceptors). Patients will be required to stand on the plates, barefoot and with knees slightly ben | 16 | Active |
| Control group | Control group (CON) | NA | 12 weeks | The CON group will continue to receive standard care for the intervention period, and will be instructed to continue with their normal daily activities for the three month period. | 15 | Active |

## ELIGIBILITY CRITERIA

| List inclusion criteria | List exclusion criteria | Min age | Max age | Gender |
|---|---|---|---|---|
| Older than 18 years Have been diagnosed with RA (according to the 1987 ACR criteria) at least three years previously On stable drug therapy (prednisone <10mg/day) Had been on stable drug therapy for at least three months previously. | HIV+ Using bisphosphonates or corticosteroids Have any co-morbidities that could potentially impact on physical activity levels Using assistive walking devices Have previously had hip or knee joint replacement surgery Are pregnant. | 18 Years | 100 Years | Female |

## ETHICS APPROVAL

| Has the study received appropriate ethics committee approval | Date the study will be submitted for approval | Date of approval | Name of the ethics committee |
|---|---|---|---|
| Yes | | 2013/02/18 | University of the Witwatersrand Human Research Ethics Committee |

### Ethics Committee Address

| Street address | City | Postal code | Country |
|---|---|---|---|
| Senate House, 1 Jan Smuts Avenue, Braamfontein | Johannesburg | 2000 | South Africa |

## OUTCOMES

| Type of outcome | Outcome | Timepoint(s) at which outcome measured |
|---|---|---|
| Primary Outcome | Bone mineral density | Baseline Follow up (three months post baseline) Post intervention (six months post baseline) |
| Secondary Outcome | Functional ability | Baseline Follow up (three months post baseline) Post intervention (six months post baseline) |
| Secondary Outcome | Physical activity | Baseline Follow up (three months post baseline) Post intervention (six months post baseline) |
| Secondary Outcome | Health related quality of life | Baseline Follow up (three months post baseline) Post intervention (six months post |

| | | |
|---|---|---|
| | | baseline) |
| Secondary Outcome | Body composition | Baseline Follow up (three months post baseline) Post intervention (six months post baseline) |

**RECRUITMENT CENTRES**

| Name of recruitment centre | Street address | City | Postal code | Country |
|---|---|---|---|---|
| Chris Hani Baragwanath AcademicHospital | 26 Chris Hani Road, Soweto | Johannesburg | 2013 | South Africa |

**FUNDING SOURCES**

| Name of source | Street address | City | Postal code | Country |
|---|---|---|---|---|
| Connective Tissues Research Grant | | | | |
| National Research Foundation | | | | |
| Carnegie Large Research Grant | | | | |

**SPONSORS**

| Sponsor level | Name | Street address | City | Postal code | Country | Nature of sponsor |
|---|---|---|---|---|---|---|
| Primary Sponsor | Alessandra Prioreschi | 7 York Road Parktown | Johannesburg | 2009 | South Africa | University |

**COLLABORATORS**

| Name | Street address | City | Postal code | Country |
|---|---|---|---|---|
| Mohamed Amin Makda | 26 Chris Hani Road, Soweto | Johannesburg | 2013 | South Africa |
| Mohammed Tikly | 26 chris Hani Road, Soweto | johannesburg | 2013 | South Africa |
| Joanne McVeigh | 7 York Road Parktown | Johannesburg | 2009 | South Africa |

**CONTACT PEOPLE**

| Role | Name | Email | Phone | Fax |
|---|---|---|---|---|
| **Principal Investigator** | Ms Alessandra Prioreschi | alessandraprioreschi@ gmail.com | 0839890070 | |

| Street address | City | Postal code | Country | Position / Affiliation |
|---|---|---|---|---|
| 7 York Road, Parktown | Johannesburg | 2009 | South Africa | Researcher |

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| **Scientific Enquiries** | Prof Mohammed Tikly | drmohammed@gmail.com | +27119339377 | |

| Street address | City | Postal code | Country | Position / Affiliation |
|---|---|---|---|---|
| 26 Chris Hani road, Soweto | Johannesburg | 2013 | South Africa | Head of Rheumatology |

| Role | Name | Email | Phone | Fax |
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| **Public Enquiries** | Ms Alessandra Prioreschi | alessandraprioreschi@ gmail.com | 0839890070 | |

| Street address | City | Postal code | Country | Position / Affiliation |
|---|---|---|---|---|
| 7 York Road, Parktown | Johannesburg | 2009 | South Africa | Researcher |

## Changes to trial information

| Date | Reason | Old Value | Update Value |
| --- | --- | --- | --- |