Investigating plantar pressure measurements and their potential role in a local diabetes foot screening pathway

Feasibility study

Version 1.6
20/06/2019

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TITLE
Investigating plantar pressure measurements and their potential role in a diabetes foot screening pathway

STUDY MANAGEMENT GROUP

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Co-investigator:	Dr Kirsty Wood Clinical Development Fellow Raigmore Hospital
Co-investigator:	Mr James Beastall Consultant Orthopaedic Surgeon Raigmore Hospital
Co-investigator:	Dr Mark Grindle Senior Lecturer in Digital Health

STUDY CENTRE

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CLINICAL QUERIES

Clinical queries should be directed to Professor Sandra MacRury, Chief Investigator (see above), who will direct the query to the appropriate person.

SPONSOR **UHI**

CO SPONSOR **NHS Highland**

AMENDMENT HISTORY

Amendment	Protocol Version	Date	Author(s) of Changes
	1.1	05/12/18	Professor MacRury
Updated details on inclusion and exclusion criteria	1.2	18/01/19	Dr Kirsty Wood
Updated participant recruitment details and objectives	1.3	10/02/19	Dr Kirsty Wood
Updated sponsor information	1.4	18/03/2019	Dr Kirsty Wood
Updated title	1.5	20/03/2019	Dr Kirsty Wood
Updated method, no longer using Moticon insoles due o problems with connectivity prior to commencing data collection	1.6	20/06/2019	Dr Kirsty Wood

STUDY SYNOPSIS

Title	Investigating plantar pressure measurements and exploring their role in a local diabetes foot screening pathway
Rec. reference:	
Participants (Inclusion criteria)	Adult men and women aged over 18 Any form of diabetes Attends Raigmore diabetes clinic Able to understand the patient information leaflet, able to consent and be consented.
Exclusion criteria	Under 18 Pregnant women Unable to walk unaided Amputees, foot injuries, foot disease not related to diabetes Unable to consent or not able to understand the participant information leaflet.
Control group	Age, gender, BMI matched group A separate group of non-diabetic volunteers
Sample size	Pilot study so no power calculation applied. n=60
Duration	4 months
Primary objective	To determine whether plantar pressure measurements can be reliably measured with the Footscan platform.
Secondary objective	The comparison of pressure measurements between people with and without diabetes and if there is a pattern of pressures in people with diabetic foot disease.
Measurements	Plantar pressure measurement from Footscan system. Height and weight.

Study process	**Participant recruitment** • Researcher will identify potential participants from patient health records and consultation with diabetes specialist staff in the clinic. They will be approached by researcher or podiatrist either at clinic attendance or through referral from diabetes specialist staff. • A group of age, gender and BMI matched non-diabetic individuals will be identified from other medical outpatient clinics e.g. renal, hypertension, and cardiology through discussion with the consultant leading the clinic. • A further group of non-diabetic individuals with no foot problems from the Centre for Health Sciences will be approached by researcher. • Potential participants will be contacted by the Chief Investigator as appropriate. • Participant information sheets will be provided for potential participants who express an interest in taking part in the study. • Posters will be displayed in outpatient clinic areas and in centre for health sciences. **Prior to enrolment in the study** • Obtain written informed consent **Study process** **Before clinic for participants with diabetes** • Gathering patient data including type of diabetes, foot screening history **At clinic** • Plantar pressure measurements using Footscan system • Weight required to calibrate Footscan

TABLE OF CONTENTS

GLOSSARY OF ABBREVIATIONS

KEY WORDS
Diabetes

1. INTRODUCTION

1.1. Background

Diabetes is a common chronic medical condition which is associated with significant morbidity and mortality. The prevalence of diabetes is increasing and by 2025, it is estimated that around 5 million people in the UK will have a diagnosis of diabetes.[1]

The 2016 Scottish Diabetes Survey reported that 5.4% of the population was recorded as having a diagnosis of diabetes. 88.3% of these people had Type 2 diabetes and 10.6% had Type 1.[2]

The NHS Highland health board had 17,100 people on the diabetes register at the end of 2016. The crude prevalence of diabetes in this region has increased from 4.9% to 5.2% in two years. [2]

There are many complications associated with diabetes, broadly categorised as large vessel arterial disease, including myocardial infarction, stroke and peripheral vascular disease and microangiopathy, with renal disease and retinopathy being examples.[3]

People with diabetes are at increased risk of foot complications due to peripheral neuropathy and/or peripheral arterial disease.[1] 5.7% of people with Type 1 diabetes and 3.9% of those with Type 2 in NHS Highland have a record of having had a foot ulcer.[2]

Management of foot problems related to diabetes presents significant financial cost to the NHS through primary and community care, outpatient costs, inpatient bed occupancy and prolonged hospital stays. It has been estimated that £650 million is spent by the NHS on foot ulcers and amputations per year.[4]

In an effort to detect problems early and prevent foot ulceration, foot care screening programmes for people with diabetes are common practice. It is recommended that people are screened at diagnosis and annually thereafter by examining for neuropathy using a 10g monofilament, peripheral pulses and observing for ulceration, callus or deformity.[1]

A person is then assigned a low, moderate, high or active risk category allowing referral of appropriate people for multidisciplinary foot care or protection.[1]

1.2. Rationale for current study

Although recommendations around foot screening exist, there is considerable variation in practice.[1] Systematic reviews have shown problems with monofilament testing, reporting limited sensitivity due to variability in number of foot sites tested and location of these test sites.[5]

Elevated plantar pressure measurements while walking have been increasingly recognised as a risk factor for foot ulceration. A study in the 1960s first showed that foot ulcers in leprosy tended to occur in areas of highest plantar pressure. Since then, with emerging technologies, studies have shown that dynamic plantar pressures are generally higher at the ulcer or previous ulcer location but a pressure threshold that predicts foot ulceration has not yet been identified.[6]

This study aims to explore whether a technological device used to measure plantar pressures could act as a more accurate, standardised screening method for foot complications in diabetes. Potentially, the plantar pressure measurements could then be used in the production of individualised off loading insoles or footwear.

The Footscan device, is a 1048mm x 418mm x 12 mm platform with 8192 sensors designed to be placed on the floor to provide static or dynamic plantar pressure data as the person

stands on or walks across the plate. A study on healthy people showed the Footscan platform has shown good repeatability and it is therefore possible to use it in assessment of plantar pressure distribution.[7]

This device produces pressure measurements which can be viewed on a laptop, giving potential to link up with the existing NHS diabetes database.

So far, this device has been used by professionals in the fields of sports and biomechanics. In order to identify whether there is a role in foot screening in diabetes, we must test the plantar pressures of healthy people, people with diabetes and those with known diabetic foot complications to first of all identify normal values and then the values which would indicate those with feet at risk of ulceration.

2. AIMS

This feasibility study aims to explore whether the Footscan device used to measure plantar pressures could act as a more accurate and quantifiable, standardised screening method for foot complications in diabetes.

2.1. Primary objective

The primary outcome measure will be whether plantar pressure measurements can be reliably measured with the Footscan platform in a clinic setting.

2.2. Secondary objective

The secondary outcome measure will be the comparison of pressure measurements between people with and without diabetes and if there is a pattern of pressures in people with diabetic foot disease.

3. STUDY DESIGN

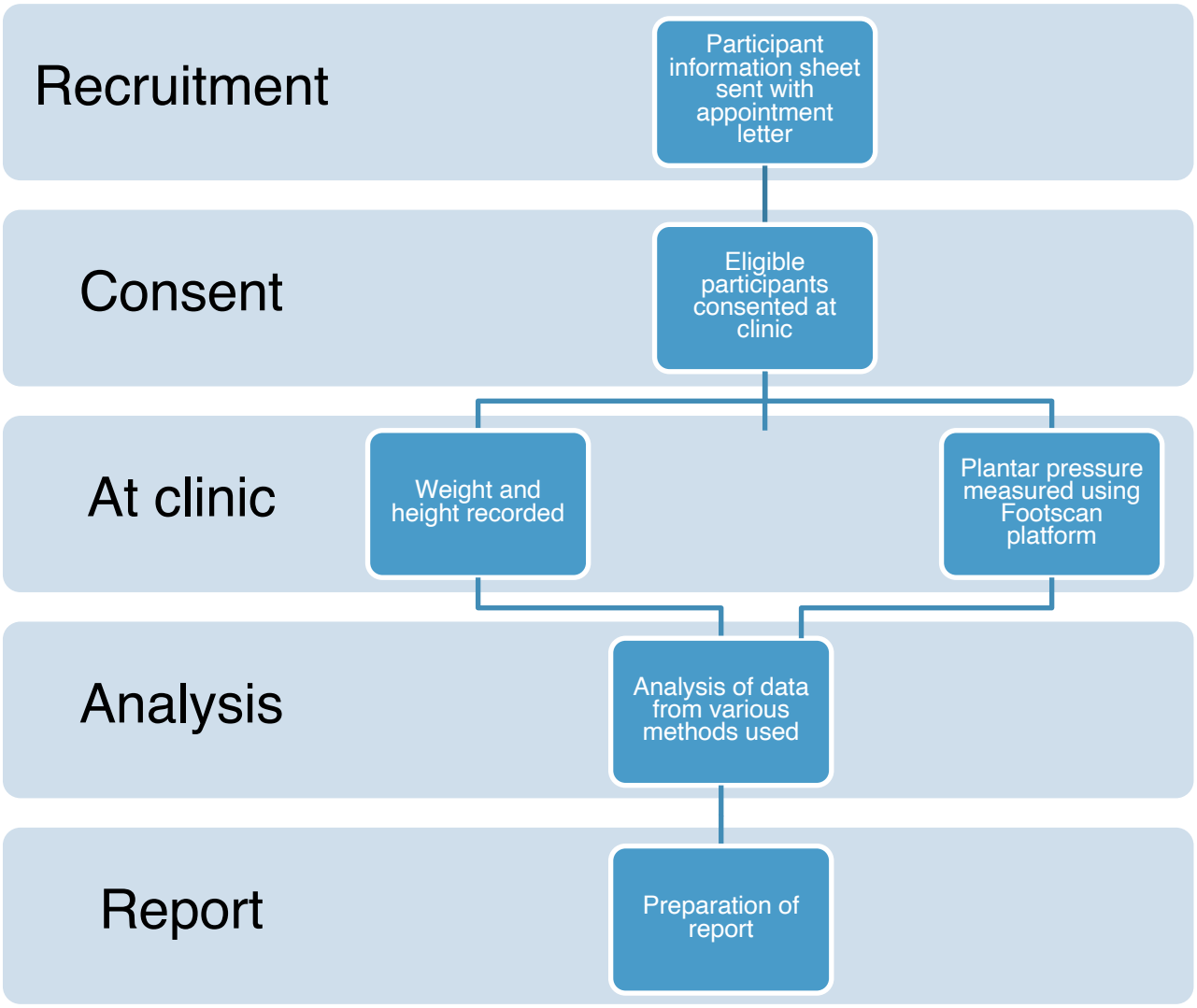
3.1. Methodology

Feasibility study.

3.2. Sample size

No power calculation. Previous experience and clinic size suggest a total of n=30 people with diabetes and n=30 control subjects (15 age, gender and BMI matched and 15 volunteers from centre for health sciences.

3.3. Study overview



4. PARTICIPANT ENTRY

4.1. Population

Participants will be recruited from the diabetes population attending the diabetes clinics at Raigmore Hospital in Inverness.

4.2. Inclusion criteria

- Adult men and women 18 to 85 years of age.
- Any form of diabetes
- Attends Raigmore diabetes or retinal screening clinic
- Able to walk unaided
- Able to understand the patient information leaflet, able to consent and be consented.

4.3. Exclusion criteria

- Under 18 years
- Pregnant women
- Unable to walk unaided
- Lower limb amputees
- Previous or current foot injuries, operations.
- Unable to consent or not able to understand the participant information leaflet.

4.4. Withdrawal criteria

Participants will be withdrawn immediately from the study if they express a wish to do so.

5. ENROLMENT PROCEDURES

Potential participants will be identified by the either the CI or co-investigators when attending a routine diabetes or retinal screening clinic.

A group of age, gender and BMI matched non-diabetic individuals will be identified from other medical outpatient clinics e.g. renal, hypertension, and cardiology through discussion with the consultant leading the clinic.

They will have received an invitation letter and Participant Information Sheet in the post with their clinic appointment letter, approximately 2 weeks prior to clinic attendance.

A further group of healthy individuals from the Centre for Health Sciences will be approached by the researcher.

Participants who express an interest in participating will be provided with an Invitation Letter accompanied by a Participant Information Sheet. Participants who agree to participate will then have informed consent taken prior to participating and recorded on consent form.

6. STUDY PROCEDURES

6.1. Informed consent

Participants will be asked to give informed written consent for participation in the study.

Participants will give informed written consent for:

- Weight and height recording, or measurement if no recent record
- Having plantar pressures measured by walking on Footscan system
- Allowing the findings to be used in an anonymous form

6.2. Weight and height

The patient will have weight measured on scales and height with stadiometer if not recently recorded. This is measured due to Footscan requiring weight calibration and also to allow BMI calculation.

6.4. Measuring plantar pressures with Footscan platform

The Footscan platform will be placed on the floor. The participant will stand on the plate without shoes or socks to record static pressure measurement. They will then walk across the plate, three times to obtain three recordings of each foot. The data is downloaded at the time of recording. The plate will be cleaned with hard surface wipes in between each participant.

6.5. Duration of participation

Participants will be considered to be in the study from the time of giving informed consent until they have attended clinic for plantar pressure measurements. Participation is expected to be approximately 30 minutes at the clinic.

6.6. Data recording and storage

Initially, pressure data will be recorded and saved on Footscan computer software in anonymised personal folders for each participant. A data collection form will be used to collect age, weight, height, type of diabetes and information on current foot health. Information will then be transferred to a database on password protected computer to which only the main investigators and delegated researcher will have access.

7. STATISTICAL PLAN

Descriptive analysis of data will be performed.

8. MONITORING

8.1 Risk assessment

This study will be low risk as only involves participants with good mobility, walking short distances.

8.2 Monitoring at study centre

All consent forms will be checked by the delegated researcher.

9. REGULATORY ISSUES

9.1 Ethics approval

Application for research ethical approval was gained on 24/04/2019 from the West of Scotland Research Ethics Service.

9.2 Consent

Consent to enter the study will be sought from each participant only after a full explanation has been given, a participant information sheet (Appendices II and III) offered and time allowed for consideration. Participants will be given the opportunity to ask any questions regarding the study. Furthermore, a consultant diabetologist not involved in the study is available for impartial advice. Signed participant consent will be obtained (Appendix IV). The right of the participant to refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time from the study without giving reasons and without prejudicing further treatment.

9.3 Confidentiality

Participant identification data will be required for the registration process. The delegated researcher will preserve the confidentiality of participants taking part in the study by application of individual study code numbers.

9.4 Sponsor

The University of Highlands and Islands and NHS Highland will co-sponsor the study.

9.5 Audits and inspections

The study may be subject to inspection and audit by University of the Highlands and Islands, by NHS Highland under their remit as co-sponsor, and other regulatory bodies to ensure adherence to GCP.

10. STUDY MANAGEMENT

A Study Management Group (SMG) will be appointed and will be responsible for overseeing the progress of the study overall. The Chief Investigator, Professor Sandra MacRury, has overall responsibility for the study, whilst day-to-day management of the study will be co-ordinated through the study researcher.

11. PUBLICATION POLICY

All publications and presentations relating to the study overall will be authorised by the SMG. The first publication of the study results will be in the name of the SMG. Named authors will include at least the study's Chief Investigator, Co-Investigators, laboratory workers and research nurse. Members of the SMG will be listed and contributors will generally be cited by name. Authorship of parallel studies initiated outside of the SMG will be according to the individuals involved in the project but must acknowledge the contribution of the SMG.

12. REFERENCES

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