PARTICIPANT INFORMATION SHEET

1. Study Title

"A Prospective Open Label pilot study investigating the impact of ThermaCare on flexibility, muscle relaxation & low back pain in two different populations."

2. Principal Investigator

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3. Introduction

<u>The following information describes the study and your role as a participant:</u>
Your study investigator will answer questions you may have about the study. The information contained in this Information Sheet will help you to understand the possible risks and benefits involved in the study, what alternatives are available and what would happen. Your rights and responsibilities will also be outlined.

This Participant Information Sheet and Consent Form tells you about the research project, and explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
- understand what you have read;
- consent to take part in the research project;
- consent to participate in the research processes that are described;
- consent to the use of your personal and health information as described.

This study has been approved by an ethics committee. Ethics committees help protect participants in research studies.

4. Purpose of the Study:

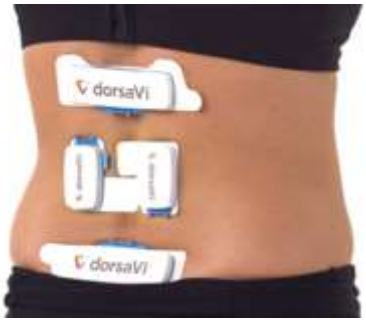
You are invited to participate in this research project. This is because you are either currently experiencing low back pain or actively play sport, and you meet the other criteria for an ideal candidate. The aim of this project it to:

Evaluate the efficacy of ThermaCare HeatWraps:
1. *As an intervention for people with low back pain.*
2. *As an intervention for people who are actively involved in sport.*

This will be achieved by comparing data from ViMove sensors obtained before, during, and after the use of ThermaCare HeatWraps.

ViMove sensors measure lumbo-pelvic movement as well as muscle activity of your back.

dorsaVi's ViMove device has been cleared by the relevant regulatory bodies for use as a medical device in Australia, New Zealand, UK & USA for the purposes of assessment and rehabilitation for low back pain.



Picture of the ViMove sensors being worn

Recording & Feedback Device that is carried with you when wearing ViMove out of clinic

ThermaCare Low back HeatWrap

5. Study Procedures:

This study will require you to wear a ThermaCare HeatWrap and ViMove sensors to monitor your movement and activity levels throughout the day. You will be asked to wear up to 4 sensors which record movement and muscle activity. Sensors will be attached by single-use, disposable adhesive pads. The pads are hypo-allergenic; however, please exclude yourself from the project if you are prone to allergic reactions to adhesives. The sensors transmit data to a small (mobile-phone sized) device. You'll be asked to keep one of these devices on your person whilst wearing the sensors out of clinic. This device can be carried in its accompanying pouch, or can be kept in your pocket or handbag, but will need to kept within 1-metre of you for the full duration of your time out of clinic.

The main study will occur on two consecutive days.

On the first day, you will be required to undergo a ViMove in-clinic assessment which assesses your performance on a range of movement tasks. You will also be required to complete 4 questionnaires. You will then leave the clinic whilst wearing the sensors, and go about your day. This will monitor your activity levels for the remainder of the day.

You will be required to return to the clinic at the end of the same day (approximately 8-hours after the morning visit) to have the device removed, and for a few follow up questionnaires.

The second day will have an almost identical procedure, except that you will also be required to wear a ThermaCare HeatWrap in conjunction with the movement sensors. This HeatWrap will have to be worn whilst out-of-clinic as well, and will be removed upon returning to the clinic in the afternoon.

It is a good idea to wear loose clothing for these sessions (pants/skirt and top) so the clinician can easily access your back. ViMove will be worn by you in clinic to obtain information on your movement and muscle activity and will also be worn by you at home/work etc. to monitor your movement throughout the day.

Apart from not being able to shower, bath or swim during the hours that you are wearing ThermaCare and/or ViMove, there are no other restrictions to carrying on as per normal during your time out-of-clinic.

This study is being initiated and conducted by dorsaVi Ltd, and is sponsored by Pfizer Consumer Healthcare.

A total of 40 participants will be enrolled in this study from 3 physiotherapy practices in Victoria, Australia. These sites will be engaged for device fitment and performance of the in clinic assessments.

5a. Schedule and Length of Assessment

<u>Day 0 (Enrolment)</u>

1. Obtain written informed consent.
2. Ensure that the participant meets all inclusion criteria and none of the exclusion criteria.
   - Not meeting the inclusion is not a reflection on your health or anything else, other than that all participants in a study must be as closely matched as possible with as few other conflicting conditions as possible. This is to ensure the effects of ThermaCare can be measured truthfully, and to allow a meaningful comparison.
3. Review and explain study procedures.
4. Obtain medical history and demographic information.

Day 1 **(Baseline AM)** within 3 weeks of - or on the same day as enrolment
1. Questionnaire Package – 15 minutes
2. ViMove in clinic assessment – 20 minutes
3. ViMove monitoring assessment ~ 8 Hours (sensors worn out of clinic)

This appointment will be anywhere from 8 a.m. – 11 p.m.

Day 1 **(Baseline PM)** Same day as Baseline AM
1. Questionnaire Package – 15 minutes
2. ViMove in clinic assessment – 20 minutes
3. Sensors removed and returned to the clinician.

This appointment will be approximately 8 hours after your previous appointment.

Day 2 **(Intervention AM)** Consecutive to Day 1
1. Questionnaire Package – 15 minutes
2. ViMove in clinic assessment – 20 minutes
3. ThermaCare worn on to the low back
4. ViMove monitoring assessment ~ 8 Hours (sensors worn out of clinic)

This appointment will be anywhere from 8 a.m. – 11 p.m.

Day 2 **(Intervention PM)** Same day as Intervention AM
1. Questionnaire Package – 15 minutes
2. ViMove in clinic assessment – 20 minutes
3. ThermaCare removed from the participant's back.
4. Sensors removed from back and returned to clinician.

This appointment will be approximately 8 hours after your previous appointment.

The 4 visits will take up-to 45 minutes each.

5b. Questionnaire Package

You will be required to complete 5 sets of questionnaires which assess your pain and disability levels, as well as your current emotional state. The questionnaires are as follows:

1. The Oswestry Low Back Pain Disability Index (ODI)
   - Assesses potential restrictions on activity due to low back pain
2. The Participant Global Impression of Change Scale (PGIC)
   - Assesses if you perceived changes to your low back pain during the study period
3. Numeric Rating Scale for Pain (NRS-Pain)
   - Assesses your perceived pain intensity
4. Low Back Pain Classifier (LBPC)
   - Allows a numeric classification of your pain.
5. Roland Morris Disability Questionnaire (RMDQ)
   - Assesses functional disability associated with low back pain.

6. Risks and Discomforts:

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will be looking out for side effects.

There are some potential risks, side effects and discomforts of the devices which include:

Risk	**Likelihood**	**Consequences**
Participant may experience increased Low Back Pain (LBP) as a result of performing the assessments.	Low	LBP will be managed as per participant would normally manage their LBP.
Participant may experience emotional distress during written or physical components of assessment.	Low	Participant will be supported by clinician and appropriate management will be provided.
Possible irritation of the skin from wearing ViMove.	Low	Low Skin Itching and/or discomfort for up to 24 hours.
ViMove not registering body movements.	Low	The Device will warn the investigator and patient that it can no longer provide assessment. If this occurs during a monitoring session, you need to inform your study doctor immediately.
ThermaCare related issues	Low	Skin reactions to ThermaCare. This may include itching. Subjects may also be sensitive to heat.

7. Ionising Radiation:

There will be no exposure to ionising radiation.

8. Possible Benefits:

1. Personal benefit:

The ViMove in-clinic and monitoring (out-of-clinic) assessment data will be provided to the treating clinician after the baseline and follow-up sessions. Practitioners will receive a report detailing the participant's movements during the assessment periods, and highlighting any abnormal movement patterns. The clinician may use this information to help educate the participant on healthier movement patterns and postures.

ThermaCare HeatWraps may be beneficial due to it being a heat therapy, and the normally associated effects of such therapies. However, we cannot guarantee that you will receive any benefit from this treatment.

2. Assisting in the understanding of assessment data:

This study will add to our knowledge of movement and activity in people with low back pain, and specifically how different factors related to back pain are influenced by each other.

3. This study will further our understanding of the roles of both of self-reported functional questionnaires, ViMove data, and ThermaCare in the management and prevention of Low Back Pain.

9. Alternatives to participation:

Participation is voluntary and your physician will continue with any management plan you have regardless of whether you participate in this study.

10. Pregnancy:

Pregnancy will be tested for at enrolment for Women of Child Bearing Potential.
In the event you become pregnant during the course of the study, you will be immediately withdrawn from the study. You will be invited to give consent to allow access to information regarding any pregnancy and its outcome for the purpose of determining any effects from the study.

11. Voluntary Participation/Right to Refuse or Withdraw:

There is no obligation for you to be involved in this study. If you do not participate your normal treatment plan will be followed. If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw from the study at any time without prejudice to any current or future medical treatment.

If you are not comfortable providing any specific piece of information, please inform your investigator and you will be informed as to whether this missing information requires that you discontinue the trial.

Should you choose to participate in the study, and then choose to withdraw from the study later on, you are entirely free to do so, again with no effect to the ongoing treatment and care provided to you by your practitioner.

12. Confidentiality:

The study will gather certain personal information about you. This information will be held by dorsaVi Ltd. and its authorised representatives and will be re-identifiable. Data will be re-identifiable by using the assigned participant number.

Your data will be stored at the recruitment/assessment site for a period of 5-years and will be accessed by dorsaVi Ltd. and authorised representatives. At the end of this storage period your data will be securely deleted.

Your treating doctor/s will be notified of your participation in this study and the exchange of clinically relevant information noted by the trial doctor in the conduct of the trial, will occur.

Unless required by law, only your doctor, the study team, dorsaVi and its authorised representatives, the Therapeutic Goods Administration (TGA), and the Bellberry Human Research Ethics Committee will have access to data which identifies you by name or from which your identity is otherwise apparent or can be reasonably ascertained.

All personal information will be used only for the purpose of administering your participation in this study and in accordance with the laws governing the protection and privacy of personal information under Australian privacy legislation.

By signing the attached consent form, you authorise the release of/or access to this confidential information to the relevant study personnel and regulatory authorities as noted above.

In most cases, you have the right to access personal information collected from you in connection with the study and request corrections of any such personal information that is incorrect.

13. Payment /Costs:

You will receive a total reimbursement of $200 for your participation. This will be a $100 gift card for each of the two study-related days.
Participation in the study does not cost anything. Clinic visits for the purposes of this study will not cost you anything.

14. Illness or Injury:

If, as a result of being in this study, you become ill or are injured, please immediately contact your study doctor. They will then give you all necessary information and treatment and will inform the trial sponsor.

15. Compensation for Injury:

If you are injured as a result of your participation in this investigation you may be entitled to compensation. Sponsors of clinical investigations in Australia have agreed that the guidelines developed by their industry body, Medical Technology Association of Australia (MTAA), will govern the way in which compensation claims from injured participants are managed by sponsors. However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines. These guidelines are available for your inspection on the MTAA website (www.mtaa.org.au) under Policy Initiatives – Clinical Investigations. Alternatively, your study investigator can provide you with a hard-copy of the guidelines.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

16. Termination of the Study:

Though unlikely, this research project may be stopped for a variety of reasons. These may include the following:

- Unacceptable adverse effects.
- Decisions made in the commercial interests of the sponsor.
- Project funding issues.

17. Investigators Benefits:

The principal investigator (Andrew Ronchi) is the co-founder and CEO of dorsaVi, and is not receiving any additional payment or in-kind support through his role in this study.

The co-investigators will be receiving $400 for each fully assessed participant. This will cover the time spent recruiting and screening, the 4 appointments per participant, and other administrative requirements for the study. It will also cover any venue costs.

18. New Information Arising During the Project:

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

19. Results of Project:

A summary of the results of this research will be distributed to you by your practitioner when the study is complete. This summary will not identify any individuals, but gives generic information about what results were discovered during the research.

20. Consent:

Your study doctor is required to provide you with all information regarding the nature and purpose of the research study, risks/benefits and the possibility of alternative treatment and you should be given the opportunity to discuss these. It must be stated that you are free to withdraw anytime and that if you do not participate you will not suffer any prejudice.

21. Advice and Information:

If you have any further questions regarding this study, please do not hesitate to contact any of the following staff:

- Dr. Andrew Ronchi (Principal Investigator [dorsaVi]) on (03) 9652 2192,
- Mr. Sangeeth Wanasinghage (Study Coordinator [dorsaVi]) on 0422 106 668,
- Ms. Meagan Blackburn (Co-Investigator [dorsaVi]) on (03) 9652 2198,
- Mr. Jayce Gilbert (Co-Investigator [Peak MSK Physiotherapy]) on (03) 9533 5305,
- Dr. Sallie Cowan (Co-Investigator [Clifton Hill Physiotherapy]) on (03) 9486 1918,
- Mr. Michael Tricarico (Co-Investigator [Hoppers Physio]) on (03) 9749 5110,

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies.

All study participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.

22. Complaints:

Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

Complaints can be made confidentially to the Bellberry HREC by contacting the Chief Executive Officer: Bellberry Limited, 129 Glen Osmond Road, Eastwood 5063.
Telephone 08 8361 3222. bellberry@bellberry.com.au

Consent Form

<u>Protocol Title</u>: A Prospective Open-label pilot study investigating the impact of ThermaCare on flexibility, muscle relaxation & symptoms of low back pain in two different populations.

I_____ the undersigned hereby voluntarily consent to my involvement in the research project titled:

> *"A Prospective Open-label pilot study investigating the impact of ThermaCare on flexibility, muscle relaxation & symptoms of low back pain in two different populations."*

I acknowledge that the nature, purpose and risks of the research project have been fully explained to my satisfaction by my study investigator.

Specifically, the details of the procedure(s) proposed and the anticipated length of time it will take, the frequency with which the procedure(s) will be performed and an indication of any discomfort that may be expected have been explained to me.

- I freely agree to participate in this research project according to the conditions in the Participant Information Sheet which I confirm has been provided to me.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I have been given the opportunity to have a member of my family or another person present while the study is explained to me.
- I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.
- I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event.
- I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I am 18 years of age or over.
- I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.
- I declare that all my questions have been answered to my satisfaction.
- I have read, or have had read to me in a language in which I am fluent, and I understand the Participant Information Sheet, Version 2, dated 2017/05/29.

NAME OF STUDY: *"A Prospective Open Label pilot study investigating the impact of ThermaCare on flexibility, muscle relaxation & symptoms of low back pain in two different populations."*

PARTICIPANT: _____

SIGNATURE OF STUDY PARTICIPANT: _____ DATE: _____

Declaration by senior researcher*:

A verbal explanation of the research project, its procedures and risks has been given to the participant and I believe that the participant has understood that explanation.

NAME OF SENIOR RESEARCHER:_____

SIGNATURE OF SENIOR RESEARCHER: _____DATE:_____

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* A senior member of the research team must provide the explanation and provision of information concerning the research project.

In the event that an impartial witness is required the following signing clause is to be used.

FULL NAME OF WITNESS_____
SIGNATURE OF WITNESS_____ DATE: _____

ADDRESS_____

I declare that I have been present when the research was explained to the above-named participant and to the best of my observation and belief was understood and the consent freely given.