

CLINICAL STUDY PROTOCOL

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Project Coordination Group:	<ul style="list-style-type: none">• Rob Herbert#• Gro Jamtvedt*• Alex Barratt#• Andy Oxman*• Signe Agnes Flottorp*• Kari Håvelsrud• Jan Odgaard-Jensen*
	* Norwegian Knowledge Centre for the Health Services # University of Sydney
Sponsor:	Norwegian Knowledge Centre for the Health Services, P.O. Box 7004 St Olavs plass, N-0130 Oslo, Norway. Tel.: +47 23 25 50 00. Fax: +47 23 25 50 10. Email: grj@kunnskapssenteret.no University of Sydney PO Box 170, Lidcombe NSW 1825, Australia Tel.: +61 2 9351 9380. Fax: +61 2 9351 9278 Email: r.herbert@usyd.edu.au
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1 INTRODUCTION

Many people stretch before or after exercise. This practice is based on the expectation that stretching lessens post-exercise soreness, reduces the risk of injury, increases the sense of wellbeing or enhances performance. Surprisingly, given the popularity of the practice of stretching, the effects of stretching have not been clearly established.

Biomechanical studies show that, when stretched for seconds or minutes, muscles respond viscously. Muscle viscosity manifests as stress relaxation or creep (Best et al 1994). These effects are transient, and the time course of recovery from stress relaxation is similar to the time course of the stress relaxation (Duong et al 2001). Weeks or months of regular stretching increase flexibility (Harvey et al 2002) although, at least with weeks or months of stretching of normal muscles, the increased flexibility is due primarily to an increased tolerance to stretch rather than from a change in the mechanical properties of muscles (Magnusson et al 1996).

Some evidence suggests that stretching does not prevent injury and does not reduce muscle soreness.

Herbert and Gabriel (2002) systematically reviewed the relevant randomised studies published before February 2000 and concluded, on the basis of two large randomised studies of the effects of stretching on risk of injury, that “stretching before exercising does not seem to confer a practically useful reduction in the risk of injury, but the generality of this finding needs testing”. Since that review was published several further systematic reviews of stretching on injury risk have been conducted (e.g. Weldon et al 2003, Thacker et al 2004, Rome et al 2005). A systematic review by Thacker and colleagues claimed to have identified a randomised trial of the effects of stretching on injury risk that was not included in the review by Herbert and Gabriel. However it is not clear if that trial (Andrish et al 1974), of the effects of “heel cord stretching” for preventing shin splints in navy recruits, was randomised. The trial reported incidence proportions of shin splints of 3.0% in the control group and 4.0% in the stretch group, suggesting that stretching does not produce an appreciable reduction in risk of shin splints.

Herbert and de Noronha (2007) conducted a review of studies of the effects of stretching on muscle soreness published before May 2006. The review identified 10 mostly small studies of the effects of stretching on muscle soreness. Summary estimates of effects were small. For example the effect of pre-exercise stretching was to reduce soreness one day after exercise by, on average, 0.5 points on a 100 point scale (95% CI -11.3 to 10.3; 3 studies). Post-exercise stretching reduced soreness one day after exercise by, on average, 1.0 points on a 100 point scale (95% CI -6.9 to 4.8; 4 studies). Similar effects were evident between half a day and three days after exercise. The authors concluded that “the best available evidence indicates stretching does not reduce muscle soreness”.

The existing evidence of the effects of stretching on muscle soreness and injury risk has at least two limitations. First, the studies identified in these reviews were carried out on populations that may not be representative of recreational athletes or sports people. The two trials of stretching to prevent injury risk were conducted on army recruits undergoing basic military training and nine of the 10 studies of stretching to prevent muscle soreness were carried out on participants in whom muscle soreness was induced with eccentric exercise in laboratory settings. It is not clear if the findings of these studies can be used to make inferences about the effects of stretching in the broader population of people who stretch before recreational exercise. A second limitation is that the existing studies of the effects of stretching on muscle soreness have investigated the effects of a single session of stretching or a very short program of stretching (maximum of 12 sessions over three days). However the effects of stretching may accumulate over time, perhaps because regular stretching gradually increases flexibility (Harvey et al 2002). Thus effects of stretching may not become apparent until after several months.

A very recent study examined the effects of a program of four weeks of stretching of the hamstrings muscles on muscle soreness evoked by eccentric contractions in 29 recreationally active male adults (LaRoche et al 2006). The investigators reported that the stretching program did not have a statistically significant effect on muscle soreness in the three days following exercise, but the data presented in their Figure 5 suggest stretching reduces muscle soreness 48 hours after exercise by, on average, 12.9 mm on a 100 mm scale (95% CI 5.9 to

20.0). Although this study investigated the effects of a longer period of repeated stretching than earlier studies (three sessions of stretching each week for four weeks) it was carried out on participants in whom muscle soreness was induced with eccentric exercise in laboratory settings. Thus it is still not known if regular stretching reduces muscle soreness or injury risk associated with vigorous physical activity in a community sample.

A further potential benefit of exercise is that it could improve sports performance. The only systematic review of effects of stretching on performance (Shrier 2004) concluded that the short term effect of stretching was to reduce the capacity for muscles to produce and power. Effects of stretching on running economy are unclear. Regular stretching improves muscle force, jump height and speed, although effects on running economy are again unclear.

Our informal surveys of sports-people suggest that some people stretch before or after participating in physical activity because they feel it enhances their sense of well-being or preparedness to exercise. To our knowledge these effects have not been investigated in randomised trials.

2 OBJECTIVES

The primary objectives of this trial are to determine if a program of stretching before and after vigorous physical activity reduces risk of experiencing soreness after physical activity or reduces the risk of incurring an injury while participating in vigorous physical activity.

Secondary objectives are to determine effects of stretching on the risk of injuries requiring medical attention, time to recovery, and feelings of "looseness" during and after exercise, and to ascertain if the magnitude of effects of stretching on soreness or injury risk depends on activity levels.

3 POPULATION

3.1 Inclusion criteria

To participate in the study, a person must:

1. be aged 18 years or over.
2. be able to read and write in English or Norwegian.
3. take part in vigorous physical activity (including, but not limited to, organised sport) on at least one day in the past week. (That is, answers “1” or more to Question 1 on the International Physical Activity Questionnaire.)
4. regularly access internet and email, have his or her own email address, be willing to be contacted by email on a weekly basis, and be willing to visit the trial web site and complete a brief questionnaire once per week for the 13 week trial period.
5. be willing to stop stretching (if currently stretching) or begin stretching (if currently not stretching) before and after exercise.

As the study is web-based, participation is open to people anywhere in the world who satisfy these criteria.

3.2 Exclusion criteria

A person will be ineligible to participate in the study if he or she has a lower limb or back injury that restricts participation in vigorous physical activity.

3.3 Recruitment and screening

Information about the study will be broadcast during the Norwegian Broadcasting Corporation television program “Puls” and the Australian Broadcasting Commission “Health Report” radio program in Australia. Viewers and listeners interested in participation will be invited to visit the web pages of the study to enrol. If enough participants have not registered for the trial after the initial recruitment phase, additional broadcast may be conducted to encourage more participants. Other media (such as television, newspaper advertisements and email broadcasts) may also be used to recruit participants.

Participants will be recruited into the trial through the Norwegian web site from mid-January 2008, and through the English web site from mid-February 2008.

Initial screening of potential participants will be conducted online and will be automated. There will be options for potential participants to contact the investigators by email if they have questions or would like to discuss the study in more detail. Information about the study will be provided to all potential participants on the web pages. In order to participate, interested people will have to answer several questions to ensure that they have understood the study procedures and potential risks and benefits before they consent to participation. If, after this, they agree to participate, they will verify their consent online.

The target sample size is 2321 (see 7.2: Estimation of sample size). We will, however, continue recruiting until 30 May 2007 or, in the unlikely event that we are overwhelmed with participants, until there are 5,000 participants.

3.4 Participant withdrawal

In accordance with the Declaration of Helsinki, participants will be informed that they have the right to withdraw from the study at any time.

There will be two main categories of withdrawals from the study:

Some subjects may completely withdraw from the study. Complete withdrawal involves discontinuation with the intervention (participants in the stretch group discontinue stretching, or participants in the control group take up stretching) *and* failure to report primary outcomes.

Other subjects may discontinue the intervention but report primary outcomes.

Where a participant indicates he or she wishes to discontinue the intervention she or he will be asked to continue to report outcomes. All documentation concerning the participant will be as complete as possible.

We will attempt to determine the reason for all withdrawals. The participant will be contacted by email. Withdrawals due to intercurrent illnesses or adverse events will be fully documented with the addition of supplementary information if appropriate and available.

4 PROCEDURES

4.1 Assignment to interventions

Each visitor to the trial web site will read the background information and, if interested in participation, will be screened according to inclusion and exclusion criteria. People who fulfil all of the inclusion criteria and none of the exclusion criteria will be invited to participate in the study, and to consent to participate online. They will then be asked to enter some personal data (age, gender, formal educational attainment, exercise and stretching behaviour, attitudes towards stretching and reasons for stretching). At the same time each responder will be asked to fill in their email address and a password, and informed that they will be contacted by email in a week.

One week later these people will be contacted by email and asked to visit the trial web site again. Once a person has successfully logged in and provided baseline information on all outcomes he or she will be randomly assigned to one of two treatment groups according to a pre-determined randomisation scheme. People randomised to groups will be considered to have entered the trial (that is, they will have become participants) and they will be allocated a randomisation number.

The randomisation scheme will be generated by computer. Randomisation will be unrestricted. That is, there will be no stratification or blocking.

Randomisation numbers will be assigned sequentially. The assignment will be carried out on-line by computer so there is virtually no possibility that numbers will be missed or substituted. However there will be careful scrutiny of the randomisation process and any errors concerning randomisation will be documented and explained by the investigators.

4.2 Conduct of the trial

The study will be conducted by electronic media (radio, television, email, internet). There will be no physical meetings between participants and investigators.

As part of the process of registration of interest, prospective participants will be asked to provide their email addresses and a password. This will be used to enable access to protected parts of the trial web site. The web site will provide details on how to access the web site if these details are lost. There they will provide details such as age, gender, educational status, physical activity levels and past stretching practices. They will also be asked to indicate if they have experienced bothersome soreness in their legs or buttocks or back in the preceding week.

During the study each participant will be sent an email once each week. The message will remind participants to visit the trial web site. Participants will be told they can visit the web site as often as they wish, but must do so at least once each week. If more than one week elapses between visits to the web site the participant will be asked about the period since his or her last visit to the web site. Participants who experienced an injury of the lower limb or back as a result of vigorous physical activity in the past week will be asked to provide details about the injury (date of injury, type of injury, site of injury, and the type of activity that induced the injury). All participants will be asked to provide details about whether they experienced bothersome soreness, and levels of soreness, as well as sense of "looseness" during and after exercise, amount of vigorous activity, compliance with the trial protocol, and adverse events in the past week.

After an injury, participants will be asked each week if they have recovered from injury. This will continue until the participant reports that he or she has recovered from injury, or until the end of the monitoring period (12 weeks from randomisation). On completion in the trial, participants will be sent an email message informing them that they have completed the trial and thanking them for their participation.

4.3 Scheduling of procedures

	baseline	12 weeks
	WEEK: -1 0 1 2 3 4 5 6 7 8 9 10 11 12	
	↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	
Potential participants screened for inclusion & exclusion criteria	✓	
Eligible potential participants give informed consent	✓	
Obtain contact details, baseline characteristics	✓	
Assess physical activity (IPAQ)	✓	
Randomisation	✓	
Weekly reminders to visit web site and provide data on injury and recovery from injury, soreness, vitality, compliance, physical activity and adverse events	✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓	
End monitoring, thank participant		✓
Notify participants when results available (1-2 months after completion of study)		

5 INTERVENTION

5.1 Stretch and control interventions

The following interventions will be used in the study:

5.1.1 Stretch group

Participants in the stretch group will stretch seven muscle groups (gastrocnemius, hip adductors, hip flexors, hamstrings, rectus femoris, hip external rotators and trunk rotators) on both sides of the body before and after every occasion of vigorous physical activity (Appendix 1). No other lower limb or trunk muscle groups will be stretched at any time for the 12 week period. The stretch position will be demonstrated using images on the trial web site, and participants will be able to print from the web site a credit card-sized pamphlet explaining how to carry out the stretches. Each muscle or muscle group will be stretched using a static stretch of at least 30 seconds and will be of sufficient intensity that, for the duration of the stretch, the participant feels a strong but not painful stretch.

5.1.2 Control group

Participants in the control group will be asked not to stretch any lower limb or trunk muscles at any time over the 12 week period.

5.1.3 Both groups

Participants in both groups will be instructed to continue their usual exercise patterns and their usual stretching routines for upper limbs. If participants normally warm-up prior to exercise or warm-down after exercise they will be asked to continue to perform their normal warm-up or warm-down routines, unchanged, regardless of which group they are allocated to. The exception is if a part of the warm-up or warm-down procedure provides significant stretch to the lower limbs or trunk, in which case that part of the warm-up or warm-down must be discontinued for the duration of the trial.

5.2 Duration of intervention

The intervention period will be 12 weeks.

6 OUTCOME MEASURES

6.1 Assessment of effectiveness

6.1.1 Primary effectiveness variables

Soreness

Soreness will be assessed by asking participants if, in the last week, they experienced bothersome leg or buttock or back soreness.

Time to injury

Participants will be reminded at weekly intervals to register lower limb or back injuries. Participants register their injuries on the trial web site. The participant will be asked:

- to confirm whether the injury was of the lower limb or back and whether the injury was perceived to have occurred during physical activity. (In the primary analysis we will include only injuries that are incurred during physical activity. This does not mean that symptoms must become apparent during the activity: the injury may be included in the primary analysis if symptoms develop after the activity provided that it was felt the symptoms were due to the activity.)
- whether the injury caused the participant to seek care from a health professional (see Secondary Variables below)
- the date of the injury. If the participant cannot recall the exact date of the injury he or she will be prompted to provide their best estimate of the date of injury
- the site of the injury using a modification of the report form of Fuller et al (2006)
- the nature of the injury using a modification of the report form of Fuller et al (2006)
- the number of days that elapse from the date of injury to the date of return to full participation in physical activity (see Secondary Variables below)

6.1.2 Secondary effectiveness variables

Soreness

A second measure of soreness will be obtained by asking participants to rate the worst soreness they experienced over the last week on an 11-point numerical rating scale anchored at its left end (0) with the descriptor of “no soreness” and at the right end (10) with the descriptor of “worst imaginable soreness”.

Time to injuries for which medical attention is sought

Time to injuries that might be considered could be prevented by stretching.

Classification of injuries into those which might and might not be preventable by stretching (e.g. muscle strain and fracture respectively) will be done without knowledge of which participants were in the stretch and control groups.

Time to recovery

Participants will be asked to report the number of days that elapse from the date of injury to when they feel they have recovered sufficiently from their injuries to enable them to return to the activities they were participating in immediately prior to their injuries.

“Looseness” during and after exercise

Sense of looseness” after exercise will be measured with an 11-point numerical rating scale.

6.1.3 Possible effect modifiers

Level of physical activity

The level of physical activity at baseline will be assessed with Q2 of the International Physical Activity Questionnaire.

Age

Belief in the importance of stretching

Participants will be asked at baseline the degree to which they agree with statements about the importance of stretching. Strength of agreement will be assessed on a Likert scale anchored with the terms “strongly disagree” and “strongly agree”.

6.1.4 Process variables**Compliance**

At baseline participants will be asked about how often and for how long they stretch before physical activity, and whether they enjoy stretching. Each week participants will report compliance with the trial protocol.

6.2 Adverse events and serious adverse events

Safety will be assessed by evaluation of registered adverse events. The most likely adverse events are soreness and risk of injury. Both are primary effectiveness variables.

7 STATISTICAL METHODS AND DATA MANAGEMENT

7.1 Study design

The study will be a two-armed randomised controlled trial.

7.2 Estimation of sample size

The sample size of 2388 participants provides an 80% probability of detecting a reduction in injury proportion from 12% to 8% (NNT of 25 in 12 weeks) provided the Type I error rate is set at 5%, assuming exponential hazards and a worst-case loss to follow-up of 20%.

This sample size also provides an 80% power to detect a reduction in the proportion of subjects experiencing muscle soreness from 15% to 12%, provided the Type I error rate is set at 5% and assuming a loss to follow-up of 20%. In this calculation we assumed, probably conservatively, an intracluster (within-subject) correlation of 0.4.

7.3 Randomisation

The randomisation scheme will be generated using a computerised procedure. People who visit the trial web site, indicate that they satisfy the inclusion criteria, re-visit the web site one week later, and give informed consent to participate in the trial will automatically be randomised to either a stretch group or a control group. The randomisation process will be unrestricted and, because participants recruit themselves without knowledge of which group they will be allocated to, the randomisation sequence will be concealed.

A complete randomisation list containing details of all participant numbers and their allocations will be stored as essential documentation in the Trial Master File. The randomisation list will remain concealed until completion of analysis.

7.4 Statistical analysis plan

Description of sample and outcomes: Participant characteristics and outcomes will be summarised by treatment group using, where appropriate, means, medians, standard deviations, inter-quartile ranges, minimums and maximums for continuously distributed variables; frequency counts and percents for categorical variables; and mean and median times to event, incidence rates, and Kaplan-Meier survival curves for time-to-event data.

Primary analyses: The primary analyses will compare risk of experiencing soreness and time to first injury of the stretch and control groups. All analyses will be by intention to treat. Missing data will be replaced with the last observation carried forward. The statistician will be given coded data so that he or she is blinded to allocation.

Effects of stretching on risk of soreness will be assessed using a longitudinal model. Generalised estimating equations will be used to model the log odds of having bothersome soreness. The independent variables in the model will be group membership, time, and the group by time interaction(s). The effect of stretching at each time point will be estimated with the regression coefficient(s) for the group by time interaction(s). Time will be modelled in two different ways: 1) as a continuous variable with a linear term and, if necessary, with quadratic and cubic terms; 2) as a categorical variable. The model with the best fit will be reported.

Time to first injury will be compared using Cox regression to estimate the hazard ratio and its 95% CI, provided the assumption of constant hazards appears to be met. The effect of stretching will be estimated with the regression coefficient for group.

The focus will be on estimation of the size of the effect of stretching, rather than hypothesis testing. The precision of estimates will be described with 95% confidence intervals.

Secondary analyses: A secondary test of the effects of stretching on muscle soreness will use continuous data from participants' weekly ratings of muscle soreness. Again, longitudinal models (mixed linear models with random intercepts) will be used. The same independent

variables as in the primary analyses will be included. The same approach will be used to determine effects of stretching on perceptions of looseness.

Additional secondary analyses will involve similar procedures used for testing effects of stretch on time to first injury, except that the analysis will focus only on those injuries requiring medical attention, or which are classified by an independent expert as being plausibly preventable by stretching.

Further analyses will investigate whether levels of vigorous activity levels at baseline (as measured with the IPAQ) or age or strength of belief in the importance of stretching modify effects of stretching on soreness and risk of injury. For the soreness outcome we will examine, in three separate analyses, the relevant three-way interaction term in the mixed model (activity by group by time, or age by group by time, or belief by group by time). For risk of injury we will examine the relevant two-way interaction term in a Cox regression (activity by group, or age by group, or belief by group).

Confidence intervals will be reported without adjustments for multiple comparisons, and will be interpreted in the light of number of comparisons that are made.

For the longitudinal models, sensitivity to the use of last observation carried forward for missing data will be assessed by performing similar analyses without the last observation carried forward. For each participant only weeks with a recorded value will be included in the sensitivity analyses.

Safety analysis: Safety analyses will include tabulation of type and frequency of adverse events. Any serious adverse events will be reported with comprehensive narratives.

7.5 Sample for analysis

The primary analysis of effects of stretching on muscle soreness will include all participants who answered on at least one occasion the question about whether they experienced muscle soreness in the preceding week.

The primary analysis of effects of stretching on risk of injury will include all participants (that is, all people who were randomised). In the case that a participant indicates ceases to report injury data, that person's observations will be censored immediately after their last report.

The data for each participant will be analysed in the group to which that participant was allocated, regardless of that participant's compliance with the trial protocol.

7.6 Data collection and case report forms

Participants will enter baseline data through the trial web site. The data will be stored in a database. These data, including contact details, will not be disclosed to anyone other than trial staff.

The data will not be analysed until after the desired sample size has been reached and all data have been collected for all of the included participants.

7.7 Data management

Automated validation checks will be set-up, and the participants will receive automated messages when entering inconsistent data or data that need follow-up or specific action.

Two databases will be set-up; one that includes only de-identified data of the participant (the participant is registered with initials and participant number only) and one that can identify the participant (participant identification list).

8 REGULATORY AND ADMINISTRATIVE PROCEDURES

8.1 Ethics committee

The study will be conducted in accordance with the Edinburgh (2000) amendment to the Declaration of Helsinki (1964).

The Protocol and Participant Information and Informed Consent Form have been approved by the University of Sydney Human Ethics Review Committee in Australia (approval number 12-2006/9535; 19 December 2006). If a protocol amendment is necessary this will be prepared with the agreement of the investigator, signed and submitted for ethical approval. Minor amendments that do not affect the safety or conduct of the study from the participant viewpoint, and which do not significantly reduce the scientific value of the protocol, and which do not require a significant change to be made to the consent form and/or the information sheet, will not be submitted for formal ethics review. These will be sent to the Ethics committee on an 'information only' basis.

Ethical approval is not required for this project from a Norwegian ethical review committee.

The investigator is responsible for informing the ethics committees of any serious adverse events, as described in section 6.3.2.

8.2 Participant information and informed consent

The investigator is responsible for providing to study participants on the trial web site full and adequate information about the nature, purpose, possible risk and benefit of the study. Study participants will also be notified that they are free to withdraw from the study at any time. The participants can take as much time as they need to read and understand the information before consenting (electronically).

Due to the web-based study design, only written information will be actively provided to the participant. Potential participants will be asked a series of questions to confirm that they understand the information that is provided and will have the opportunity to contact the investigators by phone or email and ask questions before deciding whether they want to participate in the study.

The consent to study participation will be given electronically (online).

A copy of the Participant Information Sheet and of the Informed Consent Form, in Norwegian or English as appropriate, will be given to the participants online.

As the study will be used for educational purposes for the TV and radio-program audience with respect to clinical trial principles, journalists will follow some of the participants in the study. The participants will be asked upon inclusion whether they would be interested in being contacted by a journalist. It will be emphasised that this is not a prerequisite for participation and that only a small number of participants will be contacted.

8.3 Participant confidentiality

The investigators will ensure that participants' confidentiality will be maintained. Case record forms and other documents stored in the clinical trial database will only identify participants by their email-addresses and study numbers. The investigator will keep a separate log of participant codes. This database will also include the electronic confirmation of the participant's consent to study participation. Each participant will be able to access her or his own data on the trial web site and no one else's.

Participants will be informed that data communicated by email cannot be guaranteed to be secure.

8.4 Good clinical practice

The study will be managed and conducted according to the latest International Committee for Harmonization Guidelines for Good Clinical Practice. The efforts of adapting the web-based

study to comply with the guidelines are discussed throughout this protocol. As the participant will not meet health care professionals face-to-face as a consequence of study participation, the procedures for adverse event reporting and obtaining of informed consent are different from other clinical trials.

8.5 Essential documents

The International Conference of Harmonisation guidelines for good clinical practice list a number of essential good clinical practice documents required prior to, during and after the conduct of the study. A complete list of essential good clinical practice documents can be found in the Investigator Site File.

8.6 Record retention

The case report forms and all medical records upon which the case report forms are based (source data) will be kept for at least 15 years after completion of the study. Image carriers or other data carriers may be used for this purpose.

8.8 Quality assurance

During or after the study is completed, sponsor representatives or regulatory authorities may wish to carry out an audit. These representatives will have the same access to study data and participant source data as the monitor.

8.10 End of trial

The end of the trial is defined as the last visit of the last participant included in the trial. The competent authorities will be notified of the end of the trial.

8.11 Study report

A study report will be prepared covering clinical and statistical aspects and summarising all findings of the clinical study.

8.12 Publication and data rights

The findings of the study will be published in a scientific journal.

The trial will be registered and assigned an ISRCTN after approval from the applicable ethics committee. The results will be refereed by experts in the fields of injury prevention and stretching and experts in clinical trial methods before being published.

The published international guidelines for authorship (International Committee of Medical Journal Editors, 1997) will be adhered to; i.e. 'All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content.'

Authorship credit will therefore be based on substantial contributions to 1) conception and design, or analysis and interpretation of data; and to 2) drafting the article or revising it critically for important intellectual content; and on 3) final approval of the version to be published. Conditions 1), 2) and 3) must all be met. Participation solely in acquisition of funding or the collation of data does not justify authorship. General supervision of the research group is not sufficient for authorship. It is intended that information on what each author has contributed will be published.

After the results have been peer reviewed, the summarised results will be made available to participants in the trial and presented on the television program NRK "Puls" and the radio program "Health Report".

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10 SIGNATURES

The protocol has been approved by:

Name and function	Signature	Date
Gro Jamtvedt Principal Investigator		
Rob Herbert Principal Investigator		
Andrew Oxman Researcher		
Alex Barratt Researcher		
Kari Håvelsrud Researcher		
Signe Agnes Flottorp Researcher		
Jan Odgaard-Jensen Researcher		

11 APPENDICES

11.2 Participant Information Statements and Consent Forms



PARTICIPANT INFORMATION STATEMENT

Randomised trial of stretching to prevent soreness and sport injuries

You are invited to take part in a research study investigating the effects of muscle stretching before and after vigorous physical activity. The main aim of the study is to determine whether stretching before and after vigorous physical activity reduces muscles soreness and risk of injury.

The study is being conducted by researchers from the Norwegian Knowledge Centre for the Health Services (Andy Oxman, Gro Jamtvedt, Signe Flottorp, Kari Håvelsrud and Jan Odgaard-Jensen) and the University of Sydney (Rob Herbert and Alex Barratt).

You have expressed an interest in the study by visiting the trial web site and submitting personal details on-line. Now you will need to choose if you wish to participate in the study. In the following paragraphs we describe what participation would involve.

Procedures

If you participate in this study you will be asked to provide some more details about yourself, including details about your exercise and stretching behaviours. Sometime in the next week you will receive an email asking you to return to this web site and provide more information. Then you will be randomly allocated to one of two groups. You will have an equal chance of being allocated to each group. For three months, participants in one group will be required to perform a particular stretching protocol before and after all occasions of vigorous activity. Participants in the other group will not stretch before or after vigorous activity for the three months.

It is important that you understand that allocation to groups will be random. This means that you will not be able to choose which group you are allocated to. You should only choose to participate in the study if you are prepared to follow *either* protocol for three months (performing a particular stretch routine for your legs and back before and after exercise *or* not stretching your legs and back at all before and after exercise).

If you choose to participate in the study we will allocate you to one of the two groups. We will tell you which group you have been allocated to and how you are to stretch (if you are in the stretch group) or not stretch (if you are in the other group).

After that we will send you email messages on a weekly basis. The email message will ask you to log on to the study web site (stretchingstudy.kunnskapssenteret.no) by using your email adress and a password chosen by yourself. You will have to answer questions about whether you have experienced any injury in the past week, and about soreness and looseness. If you have experienced an injury you will be asked to let us know the date and the nature of your injury.

It is important for the success of the trial that participants visit the trial web site and enter the data that is asked of them. If you feel you will not be inclined or able to enter the data that is asked of you then please do not agree to enter the study.

Possible risks of participation in the study

Currently it is not known whether stretching reduces muscle soreness or risk of injury. The best available evidence suggests that stretching does not prevent muscle soreness, and it does

not reduce injury risk (at least in army recruits). It is not clear how well these findings can be generalised to people such as yourself.

If (and only if) stretching does reduce soreness or risk of injury *and* if you currently stretch before and after vigorous physical activity *and* if you are allocated to the group that does not stretch you would be exposed to an increased risk of injury and soreness as a result of participation in this study.

If you experience muscle soreness or an injury we will not be able to provide treatment for you. We recommend that participants who for any reason experience disabling injuries seek appropriate care.

Confidentiality

The researchers will keep personal information they obtain from you strictly confidential. Results of this study may be used in future research and may be published, but your personal details will not be revealed.

The study will involve correspondence by email. Email correspondence is not secure, so we cannot guarantee that this correspondence will not be read by somebody other than the investigators.

Potential benefits

We do not foresee any direct benefit to you resulting from participation in this study.

Participation in and withdrawal from the study

Participation in this study is entirely voluntary. You are not obliged to participate and can withdraw from the study at any time.

Please keep this information sheet for your future reference. If you have any questions regarding this research, feel free to ask the senior Australian researchers:

Dr Rob Herbert
Associate Professor
School of Physiotherapy
The University of Sydney
PO Box 170
Lidcombe NSW 1825
stretch@health.usyd.edu.au

Dr Alex Barratt
Associate Professor
School of Public Health
The University of Sydney NSW 2006
stretch@health.usyd.edu.au

Any person with concerns or complaints about the conduct of the research study can contact the Senior Ethics Officer, Ethics Administration, University of Sydney, on (02) 9351 4811 (Telephone); (02) 9351 6706 (Facsimile) or gbriody@mail.usyd.edu.au (Email) .



Norwegian Knowledge Centre for the Health Services

The University of Sydney



CONSENT FORM

Randomised trial of stretching to prevent soreness and sport injuries

I hereby voluntarily consent to participate in the research titled “**Randomised trial of stretching to prevent soreness and sport injuries**”.

I understand that my participation in this research study is entirely voluntary. I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without this being held against me.

I have received and read the Participant Information Sheet, which describes the aims of this study, the procedures involved, and possible risks associated with participation in the study. I understand what is expected of me.

I understand that the information obtained from this research study is strictly confidential. I acknowledge that results of this study may be used in future research and may be published, provided that my personal details will not be revealed.

I understand that if I have any concerns or complaints about the conduct of the research study, I may contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811.

If I have any questions regarding this research study, I understand that I may contact Dr Rob Herbert on (02) 9351 9380 or stretch@health.usyd.edu.au.

- I consent to participate in this study
- I do not consent to participate in this study



Nasjonalt kunnskapssenter for helsetjenesten

Universitetet i Sydney



Tøyningsstudien: Deltakerinformasjon

DELTAKERINFORMASJON

Randomisert kontrollert studie av tøyning for å hindre stølhet og sportsskader

Du er invitert til å delta i en forskningsstudie som undersøker effekten av å tøye muskler før og etter hard fysisk aktivitet. Hovedmålet med denne studien er å avgjøre om tøyning før og etter hard fysisk aktivitet reduserer stølhet og risiko for skader.

Studien gjennomføres av forskere fra Nasjonalt kunnskapssenter for helsetjenesten (Gro Jamtvedt, Signe Flottorp, Andy Oxman, Kari Håvelsrud og Jan Odgaard-Jensen) og Universitetet i Sydney (Rob Herbert og Alex Barratt).

Du har vist interesse for studien ved å besøke studiens nettside og vil bli bedt om å oppgi informasjon på nettet. Du behøver ikke oppgi navn eller fødselsdato. Nå må du velge om du ønsker å delta i studien. I de neste avsnittene beskriver vi hva deltakelse innebærer.

Prosedyrer

Hvis du samtykker til å delta i studien, vil du ved neste gangs pålogging bli tilfeldig plassert i en av to grupper. Du har like stor sannsynlighet til å bli plassert i hver gruppe. I tre måneder skal deltakerne i den ene gruppen gjennomføre et bestemt tøyingsprogram for ben og rygg både før og etter hver økt med intens fysisk aktivitet. Tøyingsprogrammet tar 5-10 minutter å gjennomføre. Deltakerne i den andre gruppen skal ikke tøye ben og rygg før eller etter intens fysisk aktivitet i disse tre månedene.

Det er viktig at du forstår at fordelingen til gruppene er tilfeldig. Dette betyr at du ikke kan velge hvilken gruppe du fordeles til. Du bør bare velge å delta i studien dersom du er forberedt på å følge hvilket som helst av de to programmene (Enten å gjennomføre et bestemt tøyingsprogram for ben og rygg før og etter fysisk aktivitet eller ikke tøye ben og rygg før og etter fysisk aktivitet).

Hvis du velger å delta i studien, vil vi sende deg en e-post etter noen dager der vi ber deg logge deg på studiens nettsider med e-postadressen og passordet du selv har valgt. Vi vil spørre deg om skader, stølhet og ledighet. Deretter får du beskjed om hvilken gruppe du er plassert i, hvordan du skal tøye (hvis du er i tøyingsgruppen) eller ikke tøye (hvis du er i den andre gruppen).

Etter dette sender vi deg en ukentlig e-post (hver søndag ettermiddag). I e-postene ber vi deg logge deg på sidene og spør deg om du har opplevd noen skade i løpet av den siste uken. Vi vil også spørre deg om hvor mye muskelstølhet du har opplevd, om din følelse av løs og ledighet, og i hvilken grad du har fulgt prosedyrene i studien. Hvis du har opplevd skade, får du spørsmål om å fortelle oss når du ble skadet og hva slags skade du har.

Hvis du opplever mer enn én skade i løpet av de tre månedene studien varer, vil du ikke bli bedt om å rapportere den andre eller senere skader. Vi vil bare samle data om den første skaden.

For at studien skal lykkes, er det viktig at du som deltar besøker studiens nettside ukentlig og oppgir de dataene vi ber deg om. Hvis du tror at du ikke vil være innstilt på, eller i stand til å oppgi de dataene som vi kommer til å be om, vennligst ikke gi samtykke til å bli med i studien.

Vi vil sende en e-post med påminning etter noen dager dersom vi ikke mottar ukentlig rapport.

Mulige risikoer ved delta i studien

Per i dag er det ikke kjent om tøying reduserer muskelstørlhet eller skaderisiko. Den beste tilgjengelige forskningen antyder at tøying ikke hindrer størlhet, og at det ikke senker risiko for skade (i hvert fall ikke hos militærrekrutter). Det er ikke klart om disse funnene kan overføres til andre mennesker.

Hvis (og bare hvis) tøying reduserer størlhet eller risiko for skade, og hvis du per i dag tøyer før og etter hard fysisk aktivitet og du plasseres til gruppen som ikke skal tøye, kan du eventuelt bli utsatt for en økt risiko for skade og størlhet ved å delta i denne studien.

Hvis du får støle muskler eller blir skadet, vil vi ikke være i stand til å gi deg behandling. Hvis du av en eller annen grunn opplever skader som gjør at du må stå over flere økter med fysisk aktivitet, anbefaler vi at du oppsøker fastlegen din eller annet helsepersonell.

Konfidensialitet

Forskerne vil holde informasjon de får fra deg strengt konfidensiell. Resultatene fra denne studien kan bli brukt i fremtidig forskning og vil bli publisert, men detaljer om deg vil ikke komme frem.

Studien vil innebære korrespondanse med e-post. E-postkorrespondanse er ikke sikker, så vi kan ikke garantere at denne korrespondansen ikke vil bli lest av andre enn forskerne i studien.

Potensielle fordeler

Ved å delta i denne studien bidrar du til at vi finner svaret på om tøying reduserer risiko for skader og størlhet

Å delta i og trekke deg fra studien

Det er helt frivillig å delta i denne studien. Du trenger ikke delta, og du kan trekke deg fra studien når som helst.

Vennligst behold dette informasjonsskrivet for fremtidig bruk. Hvis du har noen spørsmål om denne studien, kontakt gjerne studiesekretariatet på e-post: toyningstudien@kunnskapssenteret.no, eller på telefon

Ansvarlig for studien er:

Gro Jamtvedt

Nasjonalt kunnskapssenter for helsetjenesten

PB 7007 St.Olavs Plass

0130 Oslo



Nasjonalt kunnskapssenter for helsetjenesten

Universitetet I Sydney



Tøyningsstudien: Samtykkeerklæring

SAMTYKKEERKLÆRING

Randomisert kontrollert studie av tøyning for å hindre stølhet og sportsskader

Jeg samtykker herved frivillig i å delta i studien ”Effekt av tøyning ved fysisk aktivitet”.

Jeg forstår at min deltakelse i denne studien er fullstendig frivillig. Jeg forstår at jeg har rett til å stille spørsmål ved hvilken som helst del av prosedyren i studien, og at jeg kan trekke meg når som helst uten at dette blir brukt mot meg.

Jeg har lest arket med deltakerinformasjon som beskriver hensikten med denne studien, prosessene/trinnene involvert, og mulig risiko forbundet med å delta i studien. Jeg forstår hva som er forventet av meg.

Jeg forstår at informasjonen denne forskningsstudien innhenter/frembringer er strengt konfidensiell. Jeg godtar at resultatene fra denne studien kan bli brukt i fremtidig forskning og skal bli publisert, under forutsetning av det ikke vil være mulig å knytte verken enkeltinformasjon eller studieresultater til meg.

Hvis jeg har noen spørsmål om denne forskningsstudien, forstår jeg at jeg kan kontakte studiesekretariatet på e-post toyningsstudien@kunnskapssenteret.no eller på telefon :

© Jeg samtykker i å delta i denne studien

© Jeg samtykker **ikke** i å delta i denne studien