CLARKSON UNIVERSITY
INFORMATION REQUIRED FOR APPROVAL OF RESEARCH WITH HUMAN SUBJECTS

GDPR-Related Research

Instructions

Before working on your protocol, please complete the online CITI Human Subjects Research training modules. The training covers concepts and laws that will help you better understand what issues to cover in your protocol. There are instructions for the training on the IRB website in the right-hand column. Select the module most appropriate to your research.

Most researchers (including faculty, grad students, and staff) will need to take the Biomedical Research, Social & Behavioral, or Data or Specimens Only (data or specimens provided by a third party such as a tissue bank) module. Undergraduate students working on minimal-risk class projects or as supervised research assistants should take the Students Conducting No More Than Minimal Risk Research module.

Undergraduate students working on more than minimal-risk class projects or as supervised research assistants should take the Biomedical Research, Social & Behavioral, or Data or Specimens Only (data or specimens provided by a third party such as a tissue bank) module. If you have questions about which module to take, please email irb@clarkson.edu for advice.

Please submit an electronic version of this form **as a Word .doc or .docx file only** by emailing it to the IRB at irb@clarkson.edu. The IRB uses Microsoft Word's Track Changes and Comment features in our review process, making it difficult to review documents in other formats.

Please include all attachments, forms, and advertisements within the one proposal file as clearly labeled appendices. **Your full protocol must arrive in the Division of Research by noon, at least two weeks prior to the meeting at which you'd like it to be reviewed**. Meeting dates are posted on our web site and announced to the campus each term. During the first week after your protocol is submitted, the IRB will contact you about any major revisions that might need to be made before the protocol can be reviewed by the full IRB.

When all required revisions have been completed, you will receive an IRB approval number. Once you have this approval number, submit one signed copy of the cover sheet (page 2 of this form) to Rebecca Thatcher, the IRB Administrative Assistant, at PO Box 5630. Signed copies should not be sent to the Chair of the IRB).

Guidelines for completing this IRB proposal form are available on the Clarkson IRB web page. If you have questions about this form or procedures, contact at IRB at irb@clarkson.edu.

(Please complete the bottom half of this page when you first submit your proposal.)

Name of Investigator: Leslie Russek, PT, DPT, PhD, OCS
Name of Investigator: Jeannie DiBon
Name of Investigator: Jane Simmonds PT Prof D, MA MSCP
(Add lines for additional Investigators.)

Name(s) of Research Assistant(s) (including staff and students):
(Add lines for additional Investigators.)

Advisor (for student research):
For students: Has your advisor read this version of the proposal and approved it for submission?
☐ Yes ☐ No

Name of department, campus mailing address, and e-mail address for primary contact and any non-Clarkson Investigators: Physical Therapy

Mailing address (if other than department): Box 5880

Title of Research: Assessing the Impact of Internet-Guided Pilates Training on People with Hypermobility

Spectrum Disorder – A Pilot Study
Date submitted: 3/10/19
Proposed start date: 4/15/19
Expected completion date: 4/15/21

If proposal is for external funding, list agency: None at this time. Depending on timing for when the project is approved and when the call for grants goes out, we may submit to the Ehlers-Danlos Society for funding.

Is this research being conducted in collaboration with another institution that has a review process? **Yes**

- **If so, list the other institution(s): University College, London**
- **If so, has this project been approved by the review board at that institution?**
  ☐ Yes ☒ No
- **If yes, please submit evidence of approval; if the proposal is undergoing review, approval by the Clarkson IRB will be contingent upon evidence of approval at other institutions.**

CLARKSON UNIVERSITY
COVER SHEET FOR IRB-APPROVED RESEARCH WITH HUMAN SUBJECTS

Complete the following information **after the proposal has been fully approved** by Clarkson's IRB and you have received an approval number. Return the signed, paper copy of this form directly to Rebecca Thatcher, the IRB Administrative Assistant, at PO Box 5630.

Title of research: **Assessing the Impact of Internet-Guided Pilates Training on People with Hypermobile Ehlers-Danlos Syndrome or Hypermobility Spectrum Disorder (hEDS/HSD)**
IRB approval number:
Proposed start date: 4/1/19
Approved until: 4/15/21 Annual Continuing Review Waived
Expected completion date: 4/15/21

The investigators and faculty advisors for this project assume the following responsibilities:

PI Responsibilities: All researcher and research assistants in contact with human subjects or with data obtained from the involvement of human subjects must be trained in human subjects research, must agree to uphold the principles of the Belmont Report and the Common Rule (described in the required training). All Primary Investigators (PI) must provide to the Division of Research certification that they have completed the on-line Human Subjects Research Certification course; PI must maintain documentation that all research assistants have completed this training. PIs for any IRB-approved research proposal (or faculty advisors, when PIs are students), are responsible for ensuring that all students and/or research assistants follow appropriate ethical procedures regarding human subjects research.

Adverse Events: You are required to immediately inform the IRB in the case of any adverse events, including exposure to risk, involving human subjects or their data. Use the Adverse Events form.

Data and Consent Forms: You should secure all identifiable data or consent documentation that is considered confidential. This usually means it is in a locked cabinet or drawer and in password-protected computers.

Protocol Modifications: You are required to submit procedural changes or amendments to this approved proposal to the IRB using the Project Modification Request; you may not make changes without IRB approval except to eliminate immediate hazards to subjects.

Continuing Review: If the research is to continue after the Approved Until date noted above, you will need to request an extension using the Continuation Request form.

Audit: The IRB audits selected research proposals to ensure that ethical procedures and the approved protocol are being followed. If your proposal is audited, you are required to comply with audit requests.

By signing, below, investigators and advisors (for student research) agree that you have read and understand the university's Policy on Research with Human Subjects, you agree to the conditions stated

above, and agree to ensure that the rights and welfare of the human participants ("subjects") are protected through your implementation or supervision.

PI Name: Leslie Russek **Sign** 

PI Name: Jeannie Di Bon **Sign** _____

PI Name: Jane Simmonds **Sign** 

(add lines for additional Investigators)

For student research: **Advisor:** _____ **Sign** _____

For faculty research: By signing, below, as Department Chair, you acknowledge that you have read the Research Summary for this project. This signature is only an acknowledgement that you have read the Research Summary, and not a promise to support or fund this research.

Department Chair: _____ **Sign:** _____

1. Research Summary (400 words or less)

People with hypermobile Ehlers-Danlos Syndrome/Hypermobility Spectrum Disorder (hEDS/HSD) often have pain, coordination problems, and low tolerance to activity and exercise. Therapeutic exercise is considered one of the most effective treatment options in the improvement of pain and disability in people with hEDS/HSD.(Engelbert et al, 2017; Simmonds et al, 2017) The Pilates Method of exercise has 6 guiding principles: centering, concentration, control, precision, flow and breathing. Pilates is a series of exercises that promote core stability, muscle strength and flexibility and attention to muscle control, posture and breathing (Wells et al, 2012). Pilates was developed for dancers who are often hypermobile, and has been recommended for people with hEDS/HSD.(McNeill, 2018) A recent systematic review concluded that Pilates is beneficial for decreasing pain and disability in a number of conditions.(Byrnes, 2018) Although a large survey of 946 people with hEDS/HSD found that 26% of respondents considered Pilates a helpful form of exercise,(Simmonds, 2017) there appears to be no research into the effectiveness of Pilates for this population.

One of the co-PI (Jeannie Di Bon) is a professional Pilates instructor who has created an internet-based Pilates course designed specifically for people with hypermobility. This course guides participants through developing body awareness and control through slow and deliberate movements. Eighty people have subscribed to this course since it was first offered in August 2016. When people purchase access to these internet modules, Ms. Di Bon is able to track how often they access the modules; hence, we would have a measure of compliance with the program.

The current research project proposes to measure pain, function, and common symptoms in individuals before and after 8 weeks of using this on-line Pilates module, and will follow up 6 months later. Before starting Pilates, subjects will complete a series of on-line questionnaires using Survey Monkey, then will progress independently through the 5 video modules, performing the exercises 3 times/week. We will track utilization of the modules on-line as a measure of compliance. At the end of the 8 weeks, we will reassess pain, function and symptoms, and we will contact subjects to collect similar data again 6 months after completing the intervention.

2. Introduction

Hypermobile Ehlers-Danlos Syndrome (hEDS) and Hypermobility Spectrum Disorder (HSD) are conditions characterized by abnormal collagen, resulting in many tissues in the body being overly flexible. Joint hypermobility is most obvious, hence the former name for this condition: joint hypermobility syndrome. HSD and hEDS comprise a continuum in which diagnostic criteria for hEDS are narrower. However, the pain and other symptoms such as sleep disturbance, fatigue, anxiety, proprioceptive (body position awareness) deficits, autonomic nervous system dysfunction, GI distress, can exist equally for both conditions.(Tinkle, 2017) The current study seeks to involve people throughout the continuum, hence hEDS/HSD.

Individuals with hEDS/HSD often have movement disorders, such as balance issues, due in part to reduced proprioception (Smith 2013), fear of movement or kinesiophobia and a reluctance to move due to the presence of chronic pain. Pain is often one of the first symptoms to appear with hypermobility (Smith 2013). Other issues such as fatigue and autonomic disorders such as Postural Orthostatic Tachycardia Syndrome (POTS) are also common in hEDS/HSD; these comorbidities can decrease desire to exercise as well as tolerance to upright (standing) exercise. Therapeutic exercise is considered one of the most effective treatment options in the improvement of pain and disability in hEDS/HSD, but optimal type, frequency and intensity are not known.(Smith, 2014; Engelbert, 2017) However, pain, fatigue and fear are common barriers to exercise among people with hEDS/HSD.(Simmonds, 2017) Mind-body exercises, such as Pilates, Tai Chi, and yoga have been recommended for people with hEDS/HSD based on the

fact that these mind-body activities are typically gentle and foster relaxation and improved body awareness.(McNeill, 2018; Russek, 2018)

Joseph Pilates (1883-1967) called his method 'Contrology' - a complete coordination of mind and body. It was only after his death, that the method grew in popularity and became known as the Pilates Method. The original 6 guiding principles of centering, concentration, control, precision, flow and breathing remain true today. The method comprises a series of exercises that promotes core stability, muscle strength and flexibility and attention to muscle control, posture and breathing (Wells et al, 2012). Pilates has become a mainstream, low-impact exercise with perceived benefits both physical (balance, flexibility, pain reduction, disability reduction) and psychological (mindfulness) (Pilates and Miller, 1998). It can be safely performed by all ages and abilities without the need for special equipment.

The Pilates Method of exercise has been widely used in physical training and rehabilitation (Latey, 2001, Kloubec 2011). Although a large survey of 946 people with hEDS/HSD found that 26% of respondents considered Pilates a helpful form of exercise,(Simmonds, 2017) there appears to be no research into the effectiveness of Pilates for this population. Used as a gentle, rehabilitation exercise method, Pilates could be a safe and effective type of exercise to manage the symptoms of pain, fatigue, disability and anxiety related to having hEDS/HSD. Furthermore, starting exercises supine (lying down) may be better tolerated by people with autonomic dysfunction, such as POTS, than exercises in the upright position.

A systematic review concluded that Pilates can be beneficial for decreasing pain and disability in a number of chronic conditions, including chronic low back pain, multiple sclerosis, and chronic neck pain.(Byrnes, 2018) However, there is no research involving people with hEDS/HSD. There are several mechanisms by which movement training such as Pilates can be beneficial for people with hEDS/HSD. One is improved muscle strength and tone, which can stabilize hypermobile joints. Another is through improved body awareness, which may improve coordination. Also, Pilates could encourage healthier breathing patterns and a calming response. Because of the proprioceptive deficits common in hypermobile individuals, use of small props like balls and bands can improve sensory awareness and help these individuals connect with their bodies.(Lauber, 2014)

Anxiety is a common symptom in people with hEDS/HSD.(Bulbena, 2017) Anxiety may be due to fear of movement associated with pain or proprioceptive deficits, or may be due to the racing heart rate associated with POTS. Kinesiophobia is an extreme fear of movement due to fear of vulnerability to pain or injury. Kinesiophobia appears to be common in hEDS/HSD, and may lead to decreased activity with resulting increased deconditioning and pain.(Celletti, 2013) Pilates has been shown to decrease kinesiophobia in patients with chronic low back pain,(Cruz-Diaz, 2018) and osteoporosis, but has not been studied in hEDS/HSD.(Oksuz, 2017)

People with hEDS/HSD appear to commonly hold their breath in an attempt to improve stability; increased tone/tension in accessory muscles of respiration (i.e., muscles other than the diaphragm, which is designed for continuous breathing) can cause pain and abnormal movement patterns. Pilates involves retaining breathing patterns, introducing simple mindfulness techniques and sensory awareness that can have an instant calming effect and reduce anxiety.(McNeill, 2017, Caldwell, 2013)

The current proposal is to study the potential benefits of an online Pilates course designed specifically for individuals with some form of hypermobility. The course was designed by a qualified Pilates teacher who also has hypermobility. Two of the PI (JDB and LR) have received very positive anecdotal feedback from people with hEDS/HSD who have taken this Pilates course. The course includes 5 modules of about 25 minutes each. Each module includes education about proper body positioning and movement, relaxation training, and Pilates exercises. The exercises are very gentle, and are often taught with modifications to make them

easier, if needed by the subject. Most are done lying down on the ground, some are done sitting in a chair, and a few are done standing. Common movement errors are explained and demonstrated to facilitate correct movement. Safety precautions (e.g., holding on to a chair back for balance during the standing exercises, if needed) are also clearly explained. In the 3 years that this course has been available to the public, the developer (JDB) has never received any feedback that the exercises caused any harm. Furthermore, a Cochrane Review of Pilates for chronic low back pain including 10 studies and 510 patients found minor or no adverse events in any of the research studies involving Pilates exercises.(Yamoto, 2015) Consequently, Pilates can be considered a very safe form of exercise.

Subjects will be asked to do their Pilates with the video at least 3 times/week, to go through the modules in order, and to complete all modules by the end of the 8th week. However, subjects may choose how often to repeat given modules, and may return to modules that they find particularly helpful. While allowing subjects this choice results in an intervention that is somewhat variable among subjects, we feel it gives subjects some ownership over their program and reproduces how the modules are used in practice.

We propose to use the following outcome measures:

- The Bristol Impact of Hypermobility (BIoH) questionnaire to measure function, quality of life, and common symptoms of hEDS/HSD. (Palmer, 2017)
- The International Physical Activity Questionnaire Short Form (IPAQ), supplemented by additional questions about mind-body and strengthening exercise, to measure physical activity.(Booth, 2000)
- The Revised Body Awareness Rating Questionnaire (R-BARQ) to measure mind-body awareness and dysfunctional breathing patterns. (Dragesund, 2018)
- The Tampa Scale of Kinesiophobia, short form (TSK-11), to measure kinesiophobia, or fear with movement.(Woby, 2005)

Our primary outcome measures will be a hypermobility-specific functional/disability measure, The Bristol Impact of Hypermobility (BIoH) questionnaire.(Palmer, 2017) The BIoH is a 55 item questionnaire that asks about pain, fatigue, joint instability, function, self-efficacy and attitudes about having hypermobility. It is the only outcome measure specifically validated for hypermobility-related conditions, and it is recommended by the international Common Data Elements initiative, whose goal is to encourage EDS researchers to use consistent outcome measures.

We will also measure physical activity, to determine whether participation in Pilates allows people to become more active. The International Physical Activity Questionnaire Short Form is a validated survey assessing physical activity during work, sport, and leisure time. (Booth, 2000) We will add questions that will track participation in mind-body exercise, such as Pilates, yoga, Tai Chi, etc. and strengthening, as these activities are not included in the IPAQ.

Kinesiophobia will be assessed through the Tampa Scale of Kinesiophobia, short form (TSK-11), which is an 11-question survey asking about fear of movement and fear of injury.(Woby, 2005) The Tampa Scale of Kinesiophobia is one of the recommended Common Data Elements for EDS. We will also collect qualitative data from weekly electronic contact.

The Revised Body Awareness Rating Questionnaire (R-BARQ) includes 12 questions that ask about body awareness, response to discomfort, breathing patters, and physical response to stress.(Dragesund, 2018) This tool may provide insight into the mechanism by which functional improvements are achieved, by correlating functional improvements with improved body awareness, relaxation, effective breathing, etc.

We will also solicit qualitative feedback about the Pilates program through weekly emails. This qualitative information will build upon a recent study using qualitative methods to assess

attitudes towards exercise among people with hEDS/HSD.(Simmonds, 2017)

The current study will repeat the questionnaires at the end of the 8 week intervention, to assess change, and again 6 months later to determine whether any changes have been maintained. We will also monitor whether subjects continue to do the Pilates exercises at 6 months, either using the videos or on their own. If findings in the current study are encouraging, a more formal randomized control trial would be an appropriate progression. The qualitative data may provide useful information about how to implement a follow-up study more effectively.

3. Objectives and Hypotheses

1. Implement a pilot study to assess whether this on-line Pilates course for people with hEDS/HSD results in beneficial changes when compared to a wait-list comparison group. We understand that the evidence will not be strong with a non-random comparison group, but having a comparison group is better than not having one. We hypothesize that 8 weeks of this specialized Pilates training will result in:
    a. Decreased pain and symptoms, improved function and quality of life (measured using the BIoH),
    b. Increased physical activity (measured using IPAQ with additional questions)
    c. Improved body awareness (R-BARQ) and less dysfunctional breathing patterns (R-BARQ)
    d. Decreased fear of movement (TSK-11).
2. Pilot test the proposed outcome measurement tools for such a future study. We are looking for basement and ceiling effects, as well as change over time.
3. Explore whether certain patterns of implementation of the on-line course are associated with better outcomes. For example, is it better to repeat one module multiple times before moving on, or to move around among modules? This will be descriptive correlational data.
4. Gather qualitative data to better understand factors that may influence compliance or maximal benefit. These data can inform future research into either Pilates or use of internet-accessible exercise training for this population. This qualitative information also provides insights into factors that influence participation in exercise within this population, and whether certain patterns are observed among people who benefit from the program compared to those who do not.

Human Subjects Protection Information

4. . Participants:

a. Number: 500 **Age range:** 18-70 **Gender:** Any, though the population is likely to be mostly female as hEDS/HSD affects more women than men.

b. Recruitment population, including inclusion/exclusion criteria:

Because the Pilates program is on-line, subjects may participate from anywhere in the world.

a. Inclusion criteria:
    i. Have some form of HSD/hEDS diagnosed by any health care provider; this would include individuals diagnosed with Joint Hypermobility Syndrome using the pre-2017 diagnostic criteria.
    ii. Able to read the English language and understand spoken English.
    iii. Willing to try to do Pilates using the 25 minute on-line training videos at least 3 times per week, unless they experience some adverse event or illness that prevents them from safely participating.
b. Exclusion criteria
    i. Medical restrictions (such as recent and healing surgery, fractures, comorbidities such as severe rheumatoid arthritis or neurological conditions, etc.) that prevent them from safely doing gentle exercise lying down on the floor, sitting, and standing.
    ii. Inability to safely stand (with or without using upper extremity for balance) for

10 consecutive minutes.

iii. Recent injuries or changes in status that are not stable. This will be defined as "A significant change in your wellness due to recent injury or new symptoms in the past month that result in your wellness during the past month being very different from the past 5 months. Flare episodes that are typical for you will not prevent you from participating at this time."
iv. Significantly changed treatment approach or medication within the past 3 months or be expecting to change their treatment program (including medication changes) during the study. This would make it difficult for us to know if changes are due to the Pilates class or the change in their treatment program. However, we understand that their health status may change such that they need to change their health care routine for physical and mental health.
v. Currently receiving regular rehabilitation such as physical therapy, or having received PT or a similar movement-based therapy (such as such as Pilates, Feldenkrais, Tai Chi, qigung, yoga) in the past 3 months. Individuals who continue to do exercises from any of these sources are not excluded, as these individuals should be stable on their current routine.
vi. Currently doing more than 30 minutes/week of Pilates exercise.
vii. Under 18 years old or over 70 years old.

c. Recruitment procedures (Attach advertisements or recruitment notices as labeled appendices. Do not begin recruiting until you have an approved protocol.):

Recruitment posters, emails and social media postings will include the information shown in Appendix A. For locations that require a shorter announcement, the brief recruitment notice (Appendix A2) will be used, and will link to the full recruitment notice.

a. The EDS Society website allows requests to be submitted online and distributed to their subscribers – link: https://www.ehlers-danlos.com/research-survey-submission/
b. Social Media via Jeannie Di Bon Facebook, Twitter and Instagram accounts
c. Social media and support groups specifically for those with EDS / HSD
d. Website announcement on www.jeanniedibon.com
e. Notice in the instructor's Pilates studio
f. Snowball sampling through current clients and database of Jeannie Di Bon, who will be given or emailed the recruitment notice. Many of the current or past clients would themselves be excluded, as they already participate regularly in Pilates. But, they may know other people who could participate.

d. Incentives and compensation

Subjects will be able to use the on-line Pilates course "*Strengthen Your Hypermobile Core*" during the study (8 weeks of intervention and 6 months of follow-up) for free . Subjects who complete the study (8 week and 6 month questionnaires) will be given permanent access to this course as incentive to complete the study.

e. Group assignment method

This is a pre-test/post-test design and all subjects will serve as their own control, as we will be measuring change over time. The wait-list group will also serve as a comparison group. Because of high demand, groups will be assigned in a pragmatic way, with those already enrolled in the immediate start group, and the next, equal number in the 8-week control group. Assignment is therefore determined by when they consent and complete the initial survey.

5. Informed Consent

a. Procedure for obtaining Informed Consent from all participants (or their parent[s] or guardian[s])? Describe who will obtain consent. (Attach Informed Consent form.)

The study will be explained on an internet page that people can access if they are interested

in participating (Appendix B). Potential subjects will read the Informed Consent document and will be allowed to contact any of the researchers if they have questions. People who choose to participate will be directed to a SurveyMonkey site that will require they agree to the Informed Consent to be able to continue to the questionnaires. Subjects will be able to withdraw from the research at any time; if they request that their data be deleted, they will lose access to the Pilates videos as access to those videos are linked to their subject identifier and data.

The Informed Consent form will ask subjects to attest to the fact that they are between 18-70 years old and that, to the best of their knowledge, they are physically able to perform the exercises safely.

We request a waiver of obtaining written informed consent on the basis that all interaction with subjects is on-line and it is not practical to obtain signed informed consent. The on-line informed consent form advises that by proceeding with the survey, they are consenting to participate.

b. If minors or other participants unable to provide legal informed consent are involved, outline procedures to be used in obtaining their agreement (assent) to participate, in addition to the consent of the parent(s) or guardian(s). (Attach assent form or statement.)
No minors will participate in this study. The questionnaires will ask each subject to verify that he/she is 18 or older. Realistically, we will not be able to verify their age. However, risk involved in participation is very low, and is no greater than daily life where they could choose to do Pilates or share some personal information on-line.

6. Study Design and Methods

a. Procedure for data collection and intervention, including duration of subject involvement:
The intervention is provided through an on-line Pilates module commercially available at https://jeanniedibon.com/strengthen-your-hypermobile-core/. "*Strengthen Your Hypermobile Core*" has 5 modules. Subjects will be asked to complete the modules in order, as the modules build upon one another. However, subjects may repeat any modules at any time, with the goal of completing all 5 modules within the 8 week period. This allows subjects the flexibility to customize their participation by using the modules they feel are most helpful. Users who typically access this Pilates course have this same flexibility so, while it adds variability to the intervention, it better reflects how the program is actually used.

Subjects will be asked to do their Pilates practice while watching the videos (not from memory) to ensure that they are performing techniques optimally. Each module lasts 25 minutes, but includes some resting activities so modules are not vigorous or fatiguing for most people. Nonetheless, subjects will be instructed to omit activities that they feel they cannot do safely. Subjects can pause a session to add more rest breaks, if needed, or stop and complete a session later. Subjects will commit to doing 3 Pilates modules per week, for a total of 75-90 minutes/week (depending on the exact length of the modules they do). The commercial application of this on-line Pilates course provides the ability to track access to each module, so we will have data regarding compliance and which modules are used at which time. Data about module utilization will be linked to the subject's self-created research code, which will keep this data anonymous as we cannot link the self-created research code to any identifiable individual.

Subjects will complete questionnaires before starting the on-line Pilates modules. Completing these questionnaires on SurveyMonkey is likely to take 30-45 minutes. These questionnaires are described in detail in section b, below.

Subjects will receive a weekly email, encouraging them to continue doing Pilates at least 3 times/week. This email will also ask them to complete some narrative questions on SurveyMonkey regarding whether they have had any problems completing the Pilates

sessions and, if so, why. We will also ask if they have any comments about the modules or about their experience. We will also ask about any changes in pain, either related to the Pilates practice, or unrelated. The contact email will also remind them that they can contact one of the PI (JD) if they have questions or problems with the Pilates, or (LR) if they have any questions about research participation.

At the end of 8 weeks, subjects will be asked to repeat the initial questionnaires on SurveyMonkey, and comment on their experience doing the Pilates. This is likely to take about 60 minutes. Subjects will continue to have access to the Pilates modules and we will encourage them to continue using the modules. We will track whether individuals do access the modules over the next 6 months.

Six months after subjects complete the 8 week exercise session, we will contact each subject again and ask him/her to repeat the initial questionnaires on SurveyMonkey, and again comment on whether they felt the Pilates was helpful.

We will also include an 8-week wait-list group constructed from subjects asking to participate after we have already recruited 225 subjects. This wait list is primarily because we do not want to be so overwhelmed by participants that we cannot manage them effectively (responding to questions about the Pilates, sending out follow-up surveys, etc.). Also, a wait-list group would provide a control group (albeit not randomly selected). All participants who do not start in the initial group will be asked if they still want to participate in a wait-list group; if they do, we will contact them 8 weeks after their initial surveys were completed, ask them to repeat the surveys, then start them in the Pilates program.

b. Measurement tools. (Attach questionnaires and surveys as labeled appendices.)

- Demographic questionnaire (see Appendix C)
- The Bristol Impact of Hypermobility questionnaire (BIoH) will be used to assess changes in pain, fatigue, self-efficacy and function.(Palmer, 2017. see Appendix D)
- The Revised Body Awareness Rating Questionnaire (R-BARQ). 12 questions. (Dragesund, 2018, Appendix E).
- The Tampa Scale of Kinesiophobia (TSK, 11 item version) will be used to assess kinesiophobia. (Woby, 2005. See Appendix F)
- The International Physical Activity Questionnaires (IPAQ) Short Form is a validated survey assessing physical activity during work, sport, and leisure time; this will be used to monitor activity level.(Booth, 2000. See Appendix G)
- Weekly Email questions for qualitative information and adverse event reporting. (Appendix H)
- Post-intervention questions for 8 weeks and 6 months (Appendix I)

c. Equipment interfacing with subjects:
Subjects will interface with the questionnaires and Pilates modules through their own computers or other electronic devices. Subjects will be asked to use a yoga mat or padded floor, small ball or towel roll, and elastic exercise band or inelastic strap to provide feedback during some of the exercises.

d. If deception is necessary, justify and describe debriefing procedures. (Attach debriefing statement as labeled appendix.) No deception is involved.

e. Analysis of outcomes:

- Quantitative data will be coded and entered into Excel, reviewed for outliers, and transferred to SPSS
- Descriptive statistics related to demographics and initial scores for BIoH, IPAQ, TSK-11, R-BARQ
- Descriptive statistics related to subjects use of the different modules (which Pilates modules were used during each of the 8 weeks and overall), and continued use of the modules through the 6 month follow-up.

- Repeated Measures ANOVA comparing pretest, post-test (8 wk) and 6 month after post-test: BIoH, IPAQ, TSK-11, R-BARQ
- ANOVA comparing change over 8 weeks for the Pilates group vs. the wait-list group: BIoH, IPAQ, TSK-11, R-BARQ
- Regression analysis using IPAQ, TSK-11, R-BARQ to predict quality of life and function as measured using BIoH before intervention, after intervention (including compliance) and 6 months later (including compliance).
- Qualitative analysis of the narrative (email) information using content analysis using the following process:(Bengtsson, 2016)
    - Decontextualization to identify meaning units, create code list
    - Recontextualization to verify that all important information has been coded
    - Categorization to organize themes, with triangulation by investigators
    - Compilation to formulate conclusions, audit, member check if subjects agree

We understand that the lack of a randomized control group makes our current design less rigorous than a randomized control trial (RCT), but having a wait-list comparison group makes the design stronger.

7. Risks and Benefits

a. Risks: detail stress, physical, psychological, social or economic harm that may be incurred by participation in this research? Describe risks (including risks associated with release of personal information) and methods for minimizing these risks.

Pilates is extremely gentle and intended to reduce pain; it is therefore unlikely that subjects will experience any pain or injury from participating in the activity. While, some soreness is always a possibility after beginning a new exercise/activity, 80 people have previously subscribed to this on-line Pilates course and none have reported any adverse effects. A systematic review of Pilates for low back pain found only 2 studies that discussed adverse events: one study reported no events and the other study reported 2 minor events.(Yamato, 2016) Furthermore, participation in this research creates no greater risk than if people signed up for this program outside of this research. Risk of harm is minimized by emphasizing self-awareness and safety during classes, and instructing subjects to omit any exercise in the videos that causes discomfort or does not feel safe to them. The disclaimer applied to all of Jeannie's on-line Pilates classes has been added to the informed consent so that the knowledge of possible risks and responses is the same for our research participants as for anyone signing up for one of her on-line courses.

There is minimal risk of private information being revealed, as subjects will use an ID code known only to them for their data on SurveyMonkey. Thus, all of the survey data will be collected, stored and analyzed without any personal identifiers. Access to the Pilates course will be tracked using subjects' email address and their self-generated research code; only Jeannie Di Bon will know subjects' email address, but she will not have access to personal information shared on SurveyMonkey. Reminder emails will be sent out by Jeannie using subjects' email address, but these emails will link to SurveyMonkey where subjects can enter their self-generated research ID. Subjects will not email any information to Jeannie as part of the research (though they are allowed to contact her independently with questions about the exercises, as are all users of her programs). Leslie and Jane will have access to the SurveyMonkey data, but will not have email addresses. Since subjects will receive access to the Pilates course free of charge, subjects will not be providing credit card information.

We will be asking for qualitative information in the weekly check-in. Although we will explicitly ask subjects to not include any identifiable information in these narrative responses, it is possible that they might. Any identifiable information will be deleted when narrative data are extracted from SurveyMonkey for further data analysis.

b. For subjects in the EU, Iceland, Liechtenstein, and/or Norway, describe how you will comply with GDPR regulations. For additional information about the GDPR, please see https://www.cnet.com/how-to/what-gdpr-means-for-facebook-google-the-eu-us-and-you/ or http://rgs.usu.edu/irb/wp-content/uploads/sites/12/2018/04/GDPR-Guidance.pdf.

According to GDPR regulations, we will be collecting Personal Data as we will be using subjects' email address to contact them, send them links to surveys, and enroll them in the Pilates course. All data entered into SurveyMonkey (all data except utilization of the on-line modules) will be through a subject-generated identification code, so the data in SurveyMonkey will be anonymous. Jeannie Di Bon, who runs the on-line Pilates courses, will have email addresses and the subject-generated ID

code so that we can track compliance, but she will not have direct access to the remaining data. All data will be stored using the subject-generated ID code. Once data collection for any individual is complete, that person's email address will be deleted from the research data, which will then be anonymous. Jeannie Di Bon will continue to have access to the email address as long as that individual wants to continue accessing the Pilates modules.

c. Address how subjects will be monitored for adverse effects and what remediation is offered.

The research will include a weekly email to touch base with each subject, reminding them to participate at the level they are comfortable (doing any, all, or no Pilates). Subjects will be asked about increased pain or problems, beyond mild soreness from doing new exercises, that they think may be due to the Pilates exercises, as that is important data. Subjects will be reminded: **"If you have increased pain or problems, either due to the Pilates exercises or any other reason, please modify or omit any or all Pilates exercises that do not feel safe to do and contact your health care provider as appropriate."** However, no remediation will be offered or provided.

Subjects

d. Does the data to be collected relate to illegal activities? If so explain. NA

e. Rate risk level. Check the most appropriate risk level below. (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

- ☒ The research involves no more than minimal risk to subjects.
- ☐ The research involves more than minimal risk to subjects but the risk(s) represents a minor increase over minimal risk, **or**
- ☐ The research involves more than minimal risk to subjects and the risk(s) represents more than a minor increase over minimal risk.

f. Methods for providing anonymity or confidentiality. For research involving patients, describe how HIPAA requirements will be met.

Each subject will create his/her own identifying code based on personal information. The identifier will be created using the following criteria:

- The 3 first letters of the month (in English) of your MOTHER'S birthday (e.g., SEP)
- YOUR 2-digit birthday date (e.g., Ø8 for May, 8th) (01-31)
- The first letter of YOUR MIDDLE NAME; enter X if you do not know or have a middle name (e.g. M for Mary) (A-Z)
- The total number of OLDER SIBLINGS you have, including living, deceased, and half (e.g., 0 if you are an only child; enter 9 if you have 10 or more siblings) (0-9)

For the examples given above, the identifier would be SEP08M0 (SEPØ8MØ). Identifiers using these variables have been shown to be highly repeatable, and there are processes for linking identifiers that are mismatched by one element.(Yurek, 2008) Once data collection is complete, all subject email addresses will be deleted from the research data. The email address will be retained by Ms. Di Bon as long as these individuals choose to use the on-line Pilates program, in the same way that typical customer information is retained. Research subjects may request that their emails be deleted by Ms. Di Bon if they no longer want to access the Pilates modules.

g. Plan for destroying private, identifiable data at the end of the research project. (You must request approval for continuation annually until all private, identifiable data has been destroyed.)

Subjects' email address is the only identifying information that is collected during this research. Once a subject has completed the study, that person's email address will be deleted from the research data. Identifying codes will be discarded after all data for a given individual have been collected and entered into the computer of the primary researcher, Leslie Russek.

h. Benefits to participants:

Subjects will be able to participate in on-line Pilates training free of charge, and will be allowed to continue using the on-line training after the research is completed.

i. Benefits to society from the research:
Very little is currently known about efficacious treatments for HSD/EDS, so this pilot study will help direct ongoing research. Also, this research establishes a format for pilot data collection for on-line training that is potentially feasible for additional interventions; this would facilitate more clinical research regarding treatments for HSD/EDS in the future. If, as anecdotal evidence suggests, Pilates is beneficial for people with HSD/EDS, this research may benefit this population by increasing awareness of this treatment approach.

j. Rate benefit level. A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences. Check the most appropriate benefit level, below:

- ☐ No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about a population group to which the subject belongs;
- ☐ No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge that may benefit a population group to which the subject belongs; or
- ☒ The research involves the prospect of direct benefit to participating subjects.

8. Investigational Device Exemption (IDE): Does this research involve any device that has not been FDA approved or which is being used for a purpose for which it has not been approved? If so, please review Clarkson's guidelines regarding IDE. What are the results of safety testing performed for this device?
NA

9. Conflict of interest statement:
One of the researchers (JD) has a financial interest in the Pilates training program being offered. While her role is essential for the intervention and data collection, data analysis will be performed by the other researchers who have no financial interest.

10. Citations

1. Bengtsson M. How to plan and perform a qualitative study using content analysis. *NursingPlus Open.* 2016;2:8-14.
2. Booth, M.L.. *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 2000;71 (2): s114-20.
3. Bulbena A, Baeza-Velasco C, Bulbena-Cabré A, et al. Psychiatric and psychological aspects in the Ehlers–Danlos syndromes. *American Journal of Medical Genetics Part C: Seminars in Medical Genetics. 2017;*175(1), 237-245.
4. Byrnes K, Wu P-J, Whillier S. Is Pilates an effective rehabilitation tool? A systematic review. *J Bodywork Movement Ther.* 2018;22(1):192-202.
5. Caldwell K, Adams M, Quin R, Harrison M, Greeson J. Pilates, Mindfulness and Somatic Education. *J Dance Somat Pract.* 2013;5(2):141-153.
6. Celletti, C., Castori, M., La Torre, G., & Camerota, F. (2013). Evaluation of kinesiophobia and its correlations with pain and fatigue in joint hypermobility syndrome/Ehlers-Danlos syndrome hypermobility type. *Biomed Res Int, 2013*, 580460.
7. Cruz-Diaz D, Romeu M, Velasco-Gonzalez C, Martinez-Amat A, Hita-Contreras F. The effectiveness of 12 weeks of Pilates intervention on disability, pain and kinesiophobia in patients with chronic low back pain: a randomized controlled trial. *Clin Rehabil.* 2018:269215518768393.
8. Dragesund T, Strand LI, Grotle M. The Revised Body Awareness Rating Questionnaire: Development Into a Unidimensional Scale Using Rasch Analysis. *Phys Ther.* 2018;98(2):122-132.
9. Engelbert, R. H. H., Juul-Kristensen, B., Pacey, V., De Wandele, I., Smeenk, S., Woinarosky, N., . . . Simmonds, J. V.. The Evidence-based rationale for physical therapy treatment of children, adolescents and adults diagnosed with joint hypermobility syndrome/hypermobile Ehlers Danlos Syndrome. *Am J Med Genet C Semin Med Genet, 2017;175*(1), 158-167.
10. Kloubec, J.A. Pilates for improvement in muscle endurance, flexibility, balance and posture, Journal of Strength Conditioning Res. 2011;24 (3) 661-667

11. Latey, P. The Pilates Method: history and philosophy, Journal of Bodywork & Movement Therapies, 2001;5(4) 275-282
12. Lauber B, Keller M. Improving motor performance: selected aspects of augmented feedback in exercise and health. *Eur J Sport Sci.* 2014;14(1):36-43.
13. McNeill WDPM, Jones SPT, Level CYQ, et al. The Pilates client on the hypermobility spectrum. *J Bodywork Movement Ther.* 2018;22(1):209-216.
14. Oksuz S, Unal E. The effect of the clinical pilates exercises on kinesiophobia and other symptoms related to osteoporosis: Randomised controlled trial. *Complement Ther Clin Pract.* 2017;26:68-72.
15. Palmer S, Cramp F, Lewis R, Gould G, Clark EM. Development and initial validation of the Bristol Impact of Hypermobility questionnaire. *Physiotherapy.* 2017;103(2):186-192.
16. Pilates J H. Miller W J 1998 – Pilates – Return to Life through Contrology, Presentation Dynamics Incorporated, Place
17. Russek LN, Stott P, Simmonds J. Recognizing and Effectively Managing Hypermobility-Related Conditions. *Phys Ther*. 2019. In press.
18. Simmonds JV, Herbland A, Hakim A, et al. Exercise beliefs and behaviours of individuals with Joint Hypermobility syndrome/Ehlers-Danlos syndrome - hypermobility type. *Disabil Rehabil.* 2017:1-11.
19. Smith TO, Jerman E, Easton V, et al. Do people with benign joint hypermobility syndrome (BJHS) have reduced joint proprioception? A systematic review and meta-analysis. *Rheumatol Int.* 2013;33(11):2709-2716.
20. Smith TO, Bacon H, Jerman E, et al. Physiotherapy and occupational therapy interventions for people with benign joint hypermobility syndrome: a systematic review of clinical trials. *Disabil Rehabil.* 2014;36(10):797-803.
21. Tinkle B, Castori M, Berglund B, et al. Hypermobile Ehlers-Danlos syndrome (a.k.a. Ehlers-Danlos syndrome Type III and Ehlers-Danlos syndrome hypermobility type): Clinical description and natural history. *Am J Med Genet C Semin Med Genet.* 2017;175(1):48-69.
22. Wells C, Kolt GS, Marshall P, Hill B, Bialocerkowski A. The effectiveness of Pilates exercise in people with chronic low back pain: a systematic review. *PLoS One.* 2014;9(7):e100402.
23. Woby SR, Roach NK, Urmston M, Watson PJ. Psychometric properties of the TSK-11: a shortened version of the Tampa Scale for Kinesiophobia. *Pain.* 2005;117(1-2):137-144.
24. Yamato TP, Maher CG, Saragiotto BT, et al. Pilates for low back pain. *Cochrane Database Syst Rev.* 2015(7):Cd010265.
25. Yurek, L. A., Vasey, J., & Havens, D. S.. The Use of Self-Generated Identification Codes in Longitudinal Research. *Evaluation Review*, 2008;*32*(5), 435–452. https://doi.org/10.1177/0193841X08316676

Appendices (Please label appendices with a letter and reference them directly in the body of the protocol above.)

A. Recruitment notice
B. Informed Consent Form
C. Demographic questionnaire
D. The Bristol Impact of Hypermobility questionnaire (BIoH) will be used to assess changes in pain, fatigue, self-efficacy and function.(Palmer, 2017)
E. Revised Body Awareness Rating Questionnaire (R-BARQ). 12 questions. (Dragesund, 2018).
F. The International Physical Activity Questionnaires (IPAQ) Short Form is a validated survey assessing physical activity during work, sport, and leisure time; this will be used to monitor activity level.(Booth, 2000)
G. The Tampa Scale of Kinesiophobia (TSK, 11 item version) will be used to assess kinesiophobia. (Woby, 2005)
H. Weekly Email questions for qualitative information.
I. 1. Email requesting people complete 8 week and 6 month surveys.

I.2. Post intervention survey (8 week and 6 month)

Appendix A: Recruitment notice

PILATES AND HYPERMOBILITY

DO YOU HAVE HYPERMOBILE EHLERS-DANLOS SYNDROME, HYPERMOBILITY SPECTRUM DISORDER, or JOINT HYPERMOBILITY SYNDROME?
WOULD YOU LIKE TO TAKE PART IN NEW RESEARCH TO ASSESS WHETHER PILATES CAN HELP WITH THE SYMPTOMS ASSOCIATED WITH THESE CONDITIONS?

The Pilates Method of exercise has been widely used in physical training and rehabilitation and research has shown that Pilates can benefit people with some chronic conditions. It has not been studied for hypermobility, but many people with hypermobility who have done Pilates in the past have said that they found it helpful. Pilates includes a series of gentle exercises that promote core stability, muscle strength and flexibility and attention to muscle control, posture and breathing.

To participate you:

- Must be between 18 and 70 years old
- Must be willing to try to do 25 minutes of Pilates, 3x/week for 8 weeks using an on-line Pilates course.
- Are able to get up and down off the floor and have no medical reason that prevents you from doing slow and gentle movements (e.g., recent fractures, neurological conditions, severe rheumatoid arthritis)
- Must be willing to answer questionnaires that ask you about your health, function and pain. This information will be confidential.
- Are not planning any major changes to your health care during the 8 week period (e.g., surgery or major medication changes) and have not had any major changes to your health care in the past 3 months (e.g., recent injury, surgery, significant changes in medications)
- Have not started or finished physical/physiotherapy, yoga, Tai Chi, qigung or Feldenkrais in the past 3 months. It is okay if you continue to do some of these exercises or activities on your own.
- Not currently be participating in more than 30 minutes/week of Pilates exercise.

Some participants will start the Pilates program immediately after completing the questionnaires, and some will be placed on a wait-list, and can start the Pilates after 8 weeks. You will have access to the online Pilates program offered through Jeannie Di Bon Movement Therapy during the study. Subjects who complete questionnaires 8 weeks and 6 months after starting Pilates will also be given permanent access to the program, which is valued at £49. Jeannie is a certified Pilates' teacher and designed the online program specifically for people with EDS / HSD.

For the purposes of this research, you would need a yoga mat or carpeted floor, a small Pilates' ball (or towel roll or pillow) and an elastic exercise band (or 1 meter long strap).

The research has been approved by the Human Subjects Research committee at Clarkson University, Potsdam, NY, USA. **Institutional Review Board (IRB) approval number**: 19-48 **Approval valid until:**

For further information about this special Pilates program, you can view the web site at: https://jeanniedibon.com/strengthen-your-hypermobile-core/. For additional information about Pilates, or to sign up, please contact Jeannie Di Bon at jeannie@jeanniedibon.com or +44 208 879 9840.

For further information about the research, please contact Dr. Leslie Russek at Lrussek@clarkson.edu.

Thank you for your interest.

Appendix A2: Abbreviated recruitment information, linking to the full recruitment notice.

Do you have Hypermobile Ehlers-Danlos Syndrome (hEDS), Hypermobility Spectrum Disorder (HSD), or Joint Hypermobility Syndrome (JHS or HMS)? Are you interested in taking part in RESEARCH to determine whether a Pilates program designed specifically for this population is beneficial? Subjects will use the program "Strengthen Your Hypermobile Core" during the study; subjects who complete the study will get permanent access to this program. Click **HERE** for more information.

(**HERE** will link to the full recruitment poster, above)

Appendix B: Informed Consent Document

Clarkson University
Documentation of Informed Consent to Participate in Research

Project Title: **Assessing the Impact of Internet-Guided Pilates Training on People with Hypermobile Ehlers-Danlos Syndrome or Hypermobility Spectrum Disorder (hEDS/HSD)**
Researcher(s): Leslie Russek, PT, DPT, PhD, OCS; Jeannie DiBon; Jane Simmonds PT Prof D, MA MSCP
Institutional Review Board (IRB) approval number: **Approval valid until:**

You have been asked to be a part of the research described here. Participation is voluntary.

Summary of the study: This study is trying to find out whether an on-line Pilates course ***"Strengthen Your Hypermobile Core"*** can benefit people with hEDS/HSD. Subjects will complete a series of on-line questionnaires asking about pain, function, and quality of life; these questionnaires will take 30-45 minutes. Subjects will then either be be given (free) access to the on-line Pilates course, or placed on an 8-week wait list before gaining access to the Pilates course. The Pilates course includes 5 modules that each last about 25 minutes; you should try to do 3 modules per week for 8 weeks. These Pilates exercises are slow, gentle movements that focus on body awareness, breathing, slow controlled movement, and relaxation; they are done lying down, sitting in a chair, or standing. We will contact you weekly to check on your progress, and ask if you have any comments or concerns. You will repeat the questionnaires after 8 weeks of doing the Pilates, and again 6 months later. While discomfort or injury are unlikely, these are always possible with a new exercise program. You may omit any exercise or movement that causes discomfort and should not do anything that you feel is not safe for you. Your privacy will be protected because survey data will be stored using an identification code that only you know; once your data collection is complete, your email address will be removed from the data and it will not be possible to link you to the data.

Please read the material below if you are interested in participating in this study.

What to expect:
Pilates exercises are slow, gentle movements that focus on body awareness, breathing, slow controlled movement, and relaxation; they are done lying down, sitting in a chair, or standing. This particular Pilates course was created specifically for people who are hypermobile. Information about ***"Strengthen Your Hypermobile Core"*** *can be found at* ***https://jeanniedibon.com/strengthen-your-hypermobile-core/*** . Subjects will complete a series of secure, on-line questionnaires asking about pain, function, and quality of life; these questionnaires will take 30-45 minutes. These questionnaires are similar to ones you complete for your health care provider, asking about symptoms, function, and quality of life. Subjects will then be either assigned to an 8-week wait list or given (free) access to the on-line Pilates course right away. The Pilates course includes 5 modules that each last about 25 minutes; you may take rest breaks or stop and return to any session, but you should try to complete 3 sessions per week for 8 weeks. If you have questions about or problems with any of the exercises, you may contact Jeannie. You will need to provide a yoga mat (or padded floor surface), a Pilates ball (or towel roll), and an elastic exercise band (or strap). We will contact you weekly to ask you to describe what you like or don't like about the exercises, any challenges you have in doing them, and any other comments you have; it will take about 10 minutes per week for you to answer these questions. We will also track which of the modules you access to better understand which modules subjects use most often and the optimal 'dose'. You will repeat the questionnaires after 8 weeks of doing the Pilates, and again 6 months later. You will continue to have access to the on-line Pilates modules during the 6 month follow-up period, and we hope that you will continue to use them if you have found them helpful.

If you have any questions about this research, you may contact Leslie Russek at Lrussek@clarkson.edu (1-315-268-3761). If you have any questions about the on-line Pilates program, contact Jeannie Di Bon jeannie@jeanniedibon.com or +44 208 879 9840.

Risks and discomforts to you if you take part in this study:
Physical risks: More than 80 people have completed this on-line Pilates course to date, and none has reported any pain or injury. While discomfort or injury are unlikely with these gentle exercises, it is always possible with a new exercise program. If you have a change in your medical status that might make it unsafe for you to continue the Pilates exercises, we recommend you contact your health care provider and limit, pause or discontinue Pilates as you feel appropriate. You may decrease the amount, pause or discontinue doing the Pilates exercises and remain

an active participant in the study if you continue completing the requested surveys. No remediation will be provided in case of increased pain that you feel is due to the Pilates exercises.

Disclaimer for all Jeannie Di Bon Wellness & Movement Pilates modules:

Clients and purchasers of any online exercise classes from Jeannie Di Bon Wellness & Movement are advised not to undertake strenuous physical activities without first seeking medical advice. If you have not exercised before or in a while, we recommend checking with your medical professional before beginning any new exercise or nutritional programme. If you are pre or postnatal please check it is safe for you to exercise or change diet. If in any doubt about your physical or mental fitness or ability to undertake any of the courses or use of the information provided on this site, you should consult your medical professional. You should also keep your medical professional informed of any change in your health which may affect your ability to exercise or follow nutritional advice given here. We request you follow all instructions given in the exercise classes carefully. It is your responsibility to ensure you are capable of undergoing a routine of exercises provided by any programme which you decide to follow. Jeannie Di Bon Wellness & Movement and Create Pilates Limited can accept no liability for personal injury related to participation in a session if a) your doctor has advised you on health grounds against such exercise b) you fail to observe instructions, techniques or advice given in any of the programmes or content provided here and c) such injury is caused by negligence of another person. We reserve the right to make alterations to any sessions or advice without notice.

Privacy risks: Each subject will create his/her own identification code based on information known to you but not sufficient for others to identify you. Jeannie Di Bon will know your email address and your identification code as part of giving you access to the Pilates course. She will also have access to data about which Pilates modules you have used during the study. She will not have access to personal information you share via questionnaires SurveyMonkey. The other researchers will have access to the SurveyMonkey data, but will not know your email and will therefore not know any identifying information about you. Your self-generated code will allow us to link your questionnaire responses before and after, your weekly comments on the Pilates program, as well as to track your use of the Pilates video modules on line. Information that you provide in the questionnaires and the weekly check-in will be collected securely using SurveyMonkey, which will not track your ISP (internet) address. Any identifiable information you may unintentionally include in the weekly narrative comments will be removed from the data before further analysis. Once all data has been collected for you, your self-created identifying code and email address will be removed from the data. Data from individual subjects will not be shared with anyone other than the researchers and results will be published with data for many subjects combined so that no individual can be identified. You may request that all data associated with you be deleted; see below for details.

The benefits to you if you take part in this study: Subjects will be able to participate in the on-line Pilates course ***"Strengthen Your Hypermobile Core"*** free of charge, and will be allowed to continue using the on-line training after the research is completed. This is a professionally developed Pilates course specifically designed for people who are hypermobile. People who have completed this program, in the past, have reported decreased pain and fewer symptoms from their hypermobility, so you may also find it beneficial.

What will you receive for taking part in this study: You will receive the on-line Pilates course ***"Strengthen Your Hypermobile Core"*** free of charge, and will be allowed to continue using the on-line training after the research is completed. This Pilates program is a £49 value.

What will happen to the information collected in this study: Each subject will create his/her own subject code based on personal information, and all data will be collected using this identifying code. We will have your email address so that we can send you links to the questionnaires and weekly check-ins, but you will enter your data directly into SurveyMonkey, which will not be able to link your data to your email. We will also be asking for weekly comments about your experience doing Pilates; if you accidentally include any identifying information in your comments, this identifying information will be deleted before data are analyzed. Once your participation in the study is finished, we will delete your email from the research data. If you choose to continue access to the Pilates program, Ms. Di Bon will still have your email address, but she will not have access to your individual research data.

The information collected will be kept confidential as much as is permitted by law.

Additional Information and Rights Under European Union General Data Protection Regulation (GDPR):[1] The GDPR provides additional rights to subjects who participate while physically in the EU, Iceland, Liechtenstein, and/or Norway.

- **Why we are using your data:** We are using the data you provide and a record of your use of the on-line Pilates course for research purposes, to find out whether people who do these Pilates exercises experience improved function and quality of life.
- **Our legal basis for using your data:** By checking the box for "I agree to participate in this research", you are giving your informed consent for us to use your data as it is described in this form.
- **How long we'll store your data:** We will store your data until results have been published. All identifying information (your email address) will be removed once your participation is complete, 6 months after finishing the 8 week Pilates module.
- **Who will view or use your data:** Only the researchers will see individual data. We may quote comments that you provide in presentations or publications, but no identifying information will be linked to those comments.
- **Where the data is stored:** Data related to use of the Pilates program will be stored in England, with Pilates instructor Jeannie De Bon. Survey and narrative data from the questionnaires and weekly questions will be stored in the United States, with researcher Leslie Russek.
- **To file a complaint about the use or protection of your data,** contact the Clarkson Institutional Review Board for Human Subjects Research: irb@clarkson.edu or 1-315-268.6475.
- **How you can withdraw consent:** *Contact one of the researchers at one of the addresses listed above.*
- **Data rights:** You have the right to access (at no cost and in easily usable format), correct, move, or request secure deletion ("right to be forgotten") of any of the personally identifiable data collected about you by contacting the researchers. You may request deletion of data associated with your subject code. When all of your data are deleted, you will no longer have access to the on-line Pilates course through this research. You may purchase the course if you want to..

What rights you have when you take part in this study: Participation in this research is voluntary. Deciding not to take part, or to stop being a part of this research will result in no penalty, fine or loss of benefits that you otherwise have a right to. If you have questions about your rights as a research subject or if you wish to report any harm, injury, risk or other concern, please contact Clarkson University's Institutional Review Board (IRB) for human subjects research: (315) 268-6475 or irb@clarkson.edu**.**

If you discontinue performing the exercises, you may still be part of this research and we hope that you will continue to complete the questionnaires at the scheduled times. If you withdraw and request that your data be removed from the study, you will also lose access to the on-line Pilates course provided to you for this research, as continued access to that course would provide further data to the researchers. If you want to continue using the on-line modules after withdrawing your data from the study, you would need to purchase the course.

Conflict of Interest: One of the researchers (Jeannie Di Bon) owns the rights to this Pilates course as part of her business. Data will be analyzed by the other two researchers, who have no financial interest in that business.

Informed Consent: Please check the boxes below to show you have had the purpose of this research explained and you have been informed of what to expect and your rights. You may contact the researchers if you have questions you would like answered before deciding whether or not to participate. You should print a copy of this consent form to keep for your records**.**

You must be able to honestly answer Yes to the following questions to be eligible for this study. If you respond "No" to any of the questions, below, you are not eligible for this study.

[1] Material in this section adapted from GDPR regulations and information from Utah State University (see https://en.wikipedia.org/wiki/General_Data_Protection_Regulation and http://rgs.usu.edu/irb/wp-content/uploads/sites/12/2018/04/GDPR-Guidance.pdf).

1. Y / N: I have been diagnosed one of the following conditions by a health care provider.
    a. Hypermobility Syndrome Disorder (HSD),
    b. hypermobile Ehlers-Danlos Syndrome (hEDS),
    c. EDS type III (EDS-III/EDS-3),
    d. EDS-hypermobility type (EDS-HT),
    e. Hypermobility Syndrome (JMS),
    f. Joint Hypermobility Syndrome (JHS).
2. Y / N: I am between 18-70 years of age
3. Y / N: I believe that I am healthy enough to participate in the Pilates exercises included in this research, as described above.
4. Y / N: This study has been adequately explained to me and I choose to participate

By clicking HERE, you agree that you have answered the above questions honestly.
BEGIN SURVEY

Appendix C: Initial Demographic and Health History

To help keep your data confidential while still being able to track changes over time, we would like you to create a research identification code that only you will know, but that you can recreate for participation in future components of this study.

__ __ __ The 3 first letters of the month (in English) of your MOTHER'S birthday (e.g., SEP)
__ __ YOUR 2-digit birthday date (e.g., Ø8 for May, 8th)
__ The first letter of YOUR MIDDLE NAME; enter X if you do not know or have a middle name (e.g. M for Mary)
__ The total number of OLDER SIBLINGS you have, including living, deceased, and half (e.g., 0 if you are an only child; enter 9 if you have 10 or more siblings)

- In this example, your identification code would be SEP08M0 (SEPØ8MØ)
- Your 7-character research code is: (provided by the computer)

5. Age: _____
6. Gender ☐Female ☐Male ☐I define myself as other than Female/Male
7. How many years ago were you diagnosed with HSD/EDS? _____
8. When did you begin to have symptoms from HSD/EDS? _____
9. Work status (check all that apply):

   ☐Full time ☐Part time ☐On disability ☐Retired ☐Unemployed ☐Student ☐Home-maker
10. Comorbidities (check all that apply):

Current Past

- ☐ ☐ Allergies
- ☐ ☐ Anxiety
- ☐ ☐ Asthma
- ☐ ☐ Chronic Fatigue Syndrome/Myalgic Encephalitis (CFS/ME)
- ☐ ☐ Degenerative spinal condition (neck, mid, or low back)
- ☐ ☐ Depression
- ☐ ☐ Diabetes
- ☐ ☐ Endometriosis, polycystic ovary syndrome or other gynecological condition
- ☐ ☐ Fibromyalgia
- ☐ ☐ Gastro-Esophageal Reflux Disorder (GERD)
- ☐ ☐ Gastroparesis or dysmotility
- ☐ ☐ Hypo/hyperthyroidism
- ☐ ☐ Irritable Bowel Syndrome (IBS)
- ☐ ☐ Mast Cell Activation Syndrome/Disorder (MCAS/D)
- ☐ ☐ Osteoarthritis
- ☐ ☐ Postural Orthostatic Tachycardia Syndrome (POTS) or orthostatic hypotension
- ☐ ☐ Raynaud's
- ☐ ☐ Rheumatoid arthritis
- ☐ ☐ Sleep disorder

Other conditions, not listed above: _____

- ☐ I have other conditions I choose not to list here

11. 5-Item Questionnaire for historical hypermobility
    - **Y / N** Can you now (or could you ever) place your hands flat on the floor without bending your knees?
    - **Y / N** Can you now (or could you ever) bend your thumb to touch your forearm?
    - **Y / N** As a child, did you amuse your friends by contorting your body into strange shapes or could you do the splits?
    - **Y / N** As a child or teenager, did your shoulder or kneecap dislocate on more than one occasion?
    - **Y / N** Do you consider yourself "double-jointed"?

12. **Y / N** Have you participated in physical therapy in the past?
    a. If Yes, how many months ago did you last get treated in PT: _____ months
13. **Y / N** Do you currently do regular exercise? If so, please check the amount

    ☐ <15 min most days, ☐ 15-30 min most days, ☐ >30 min most days

14. **Y / N** Have you participated in any Pilates in the past? If Yes: how much time/week do you spend doing Pilates exercises (enter 0 if none): _____
15. **Y / N** Have you participated in any type of mind-body training (other than Pilates) in the past? This would include Feldenkrais, Tai Chi, qigung, Yoga, etc. If Yes: what type: _____

Appendix D: Bristol Impact of Hypermobility
This form will be entered into SurveyMonkey, so formatting will change, slightly, and subjects will not be asked to compute scores.

BRISTOL IMPACT OF HYPERMOBILITY (BIOH) QUESTIONNAIRE

This questionnaire is designed to ask how hypermobility affects your day to day life. Please answer all of the questions and try not to think too much about your answer.

A. **During the past 7 days**, have you had pain in any of the following areas?

	Yes	No
Shoulders	☐	☐
Elbows	☐	☐
Wrists	☐	☐
Hands	☐	☐
Hips	☐	☐
Knees	☐	☐
Ankles	☐	☐
Feet	☐	☐
Neck	☐	☐
Back	☐	☐

B. We would like to know how often you have experienced pain and fatigue due to hypermobility during the **past 7 days.**
Please circle the number which best reflects…

1) your **average** level of pain during the **past 7 days**
0 1 2 3 4 5 6 7 8 9 10
No pain — Worst imaginable pain

2) your **worst** level of pain during the **past 7 days**
0 1 2 3 4 5 6 7 8 9 10
No pain — Worst imaginable pain

3) how much pain you have had **when walking** during the **past 7 days**
0 1 2 3 4 5 6 7 8 9 10
No pain — Worst imaginable pain

4) how much pain you have had **when resting** during the **past 7 days**
0 1 2 3 4 5 6 7 8 9 10
No pain — Worst imaginable pain

5) your **average** level of fatigue during the **past 7 days**
0 1 2 3 4 5 6 7 8 9 10
No fatigue — Totally exhausted

6) the **effect** fatigue has had on your life during the **past 7 days**
0 1 2 3 4 5 6 7 8 9 10
No effect — Large effect

7) how well you have **coped** with fatigue during the **past 7 days** *Reverse scored (0=10, 1=9, etc)
0 1 2 3 4 5 6 7 8 9 10
Not at all well — Very well

/70

C. Please tick the box which best describes how much, during the **past 7 days**, hypermobility has affected...

		Not at all[1]	A little[2]	Somewhat[3]	A lot[4]	Completely[5]
8)	the footwear you have worn	☐	☐	☐	☐	☐
9)	the transport you have used	☐	☐	☐	☐	☐

D. **How often.....**

		Never[1]	Occasionally[2]	Sometimes[3]	Often[4]	Always[5]
10)	have you had unexpected pain (that was not an expected consequence of something you have done) during the past 7 days?	☐	☐	☐	☐	☐
11)	has your wrist or hand given way, leading you to drop, or nearly drop something during the past 7 days?	☐	☐	☐	☐	☐
12)	has your ankle, knee or hip given way, leading to a stumble or trip during the past 7 days?	☐	☐	☐	☐	☐
13)	have you lost your balance during the past 7 days?	☐	☐	☐	☐	☐
14)	have joints seized up during the past 7 days?	☐	☐	☐	☐	☐
15)	has it felt like a joint has slipped out of place during the past 7 days?	☐	☐	☐	☐	☐
16)	have you had muscle cramps or spasms during the past 7 days?	☐	☐	☐	☐	☐
17)	has your sleep been disturbed due to pain or discomfort during the past 7 days?	☐	☐	☐	☐	☐

/50

E. How much difficulty have you had with the following tasks during the **past 7 days** due to hypermobility?

		Not difficult[1]	A little difficult[2]	Somewhat difficult[3]	Extremely difficult[4]	Completely impossible[5]
18)	Bending or twisting	☐	☐	☐	☐	☐
19)	Squatting	☐	☐	☐	☐	☐
20)	Walking on uneven ground	☐	☐	☐	☐	☐
21)	Carrying a heavy bag, such as a shopping bag	☐	☐	☐	☐	☐
22)	Reaching up to high shelves	☐	☐	☐	☐	☐
23)	Pulling or pushing heavy doors	☐	☐	☐	☐	☐
24)	Opening a tight or new jar	☐	☐	☐	☐	☐

		Not difficult[1]	A little difficult[2]	Somewhat difficult[3]	Extremely difficult[4]	Completely impossible[5]
25)	Writing for more than 30 minutes	☐	☐	☐	☐	☐
26)	Peeling or chopping vegetables	☐	☐	☐	☐	☐
27)	Carrying a saucepan full of water	☐	☐	☐	☐	☐

/50

F. How much discomfort would you have had after the following activities **during the past 7 days**?

		No discomfort[1]	Slightly uncomfortable[2]	Uncomfortable[3]	Painful[4]	Could not do it[5]
28)	Standing up for more than 30 minutes	☐	☐	☐	☐	☐
29)	Sitting in a chair for more than 30 minutes	☐	☐	☐	☐	☐
30)	Standing up after sitting for more than 30 minutes	☐	☐	☐	☐	☐
31)	Climbing several flights of stairs	☐	☐	☐	☐	☐
32)	Going down several flights of stairs	☐	☐	☐	☐	☐
33)	Walking at your own pace for a few miles	☐	☐	☐	☐	☐
34)	Walking briskly for a few miles	☐	☐	☐	☐	☐
35)	Wandering around shops or museums	☐	☐	☐	☐	☐
36)	Bending or twisting	☐	☐	☐	☐	☐
37)	Squatting	☐	☐	☐	☐	☐

/50

G. **Please circle** the number which best indicates...

38) how much you have felt in control of the movement of your body and limbs during the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

Completely in control — Completely unable to control

39) how accurately you have been able to predict how you might feel in general over the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

Always able to predict — Completely unable to predict

40) how frustrated you have felt with hypermobility during the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

Not at all frustrated — Very frustrated

41) how strong your body and limbs have felt generally over the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

Very strong — Extremely weak

42) how 'tight', 'strong', 'held together' your body and limbs have felt generally during the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

Very tight — Extremely loose

43) how able you have felt to control your fatigue in the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

Completely in control — No control whatsoever

44) how much you have felt in control of your pain in the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

Completely in control — No control whatsoever

45) how much you have felt in control of your life in the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

Completely in control — No control whatsoever

H. Thinking about what you are usually able to do, how much has hypermobility interfered with your activities during the **past 7 days**?

Please circle the number which best shows. . .

46) how much hypermobility has interfered with your daily activities during the **past 7 days**?

0 1 2 3 4 5 6 7 8 9 10

Not at all — Unable to do

47) how much difficulty you have had in carrying out your desired level of exercise during the **past 7 days**

0 1 2 3 4 5 6 7 8 9 10

No difficulty — Extreme difficulty

/100

I. Please tick the box which best describes your agreement with the following statements

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
48)	My body does not feel strong	☐5	☐4	☐3	☐2	☐1
49)	I am concerned about my condition getting worse	☐5	☐4	☐3	☐2	☐1
50)	I feel frustrated with my condition	☐5	☐4	☐3	☐2	☐1
51)	My coordination is poor	☐5	☐4	☐3	☐2	☐1
52)	I feel that I could trip or fall at any time	☐5	☐4	☐3	☐2	☐1
53)	I can control the movement of my limbs	☐1	☐2	☐3	☐4	☐5
54)	I feel that I can remain physically active	☐1	☐2	☐3	☐4	☐5
55)	I feel that I can manage my condition	☐1	☐2	☐3	☐4	☐5

/40

Thank you for taking the time to complete this questionnaire.

Total = /360

Appendix E:

Revised Body Awareness Rating Questionnaire (R-BARQ):

The Revised Body Awareness Rating Questionnaire

Table 5.
Final Revised Body Awareness Rating Questionnaire, With 4-Point Response Scale[a]

Item Description	Completely Disagree (0)	Somewhat Disagree (1)	Somewhat Agree (2)	Completely Agree (3)
1. I am often tense[b]				
2. My body is affected by how I feel[b]				
3. I am not aware of the way I breathe[b]				
4. I don't pay attention to the way I move[b]				
5. I struggle to relax				
6. My body is tense without me knowing why				
7. I try not to show how I'm feeling				
8. My digestion is affected by how I feel[b]				
9. I can't get comfortable when I'm lying down				
10. My body is unpredictable[b]				
11. I avoid paying too much attention to my body				
12. I don't like to be touched[b]				

[a] The items are presented in location order, with easier items on the top and more difficult items on the bottom.
[b] Also included in the original Body Awareness Rating Questionnaire.

Appendix F: The Tampa Scale of Kinesiophobia, 11-item version.

TSK-11

This is a list of phrases which other patients have used to express how the view their condition. Please circle the number that best describes how you feel about each statement.

	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree
1. I'm afraid I might injure myself if I exercise.	1	2	3	4
2. If I were to try to overcome my pain, it would increase.	1	2	3	4
3. My body is telling me I have something dangerously wrong.	1	2	3	4
4. People aren't taking my medical condition serious enough.	1	2	3	4
5. My accident/problem has put my body at risk for the rest of my life.	1	2	3	4
6. Pain always means I have injured my body.	1	2	3	4
7. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.	1	2	3	4
8. I wouldn't have this much pain if there wasn't something potentially dangerous going on in my body.	1	2	3	4
9. Pain lets me know when to stop exercising so that I don't injure myself.	1	2	3	4
10. I can't do all the things normal people do because it's too easy for me to get injured.	1	2	3	4
11. No one should have to exercise when he/she is in pain.	1	2	3	4

Source: Woby et al. (2005), Psychometric properties of the TSK-11: A shortened version of the Tampa Scale for Kinesiophobia. Pain, 117, 137-144.

Appendix G: The International Physical Activity Questionnaires (IPAQ) Short Form.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about all the **gentle** exercise that you did in the **last 7 days**. **Gentle** activities refer to activities that involve movement or body awareness, but do not make you breathe harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

7. During the **last 7 days**, on how many days did you do **gentle** physical activities like Pilates (if not included under Moderate Activity, above), Tai Chi, yoga, breathing exercises or stretching? Do not include walking.

_____ **days per week**

☐ No gentle physical activities → ***Skip to question 5***

8. How much time did you usually spend doing **gentle** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐

Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

9. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 71 (2): s114-20.

Items in green are not part of the IPAQ, but were added for purposes of the current study.

Appendix H

Weekly email/SurveyMonkey

Thank you for participating in "***Assessing the Impact of Internet-Guided Pilates Training on People with Hypermobility.***"

We hope you are continuing to do the Pilates exercises, but remember that you should only do what you feel is appropriate for you. As long as you continue to respond to the questionnaires, you are still an active research subject, independent of whether or how much Pilates exercise you do.

You may contact Jeannie Di Bon if you have questions about the Pilates program, but please do not share information regarding your response to the research questions in SurveyMonkey, as Jeannie is "blinded" to the research data (for scientific validity and to protect your private information, she is not supposed to know how individual subjects respond to the research questions). Please do not Reply to this email. If you would like to contact Jeannie with questions about the Pilates program, please email her directly at: *jeannie@jeanniedibon.com.*

Please click on the following link to go to SurveyMonkey, where we will ask you some questions about your participation. These questions will take 10-30 minutes, depending on how much you would like to share about your experience.

SURVEY MONKEY CONTENT FOR WEEKLY FOLLOW-UP EMAILS (not included in the emails)

__ __ __ The 3 first letters of the month (in English) of your MOTHER'S birthday (e.g., SEP)
__ __ YOUR 2-digit birthday date (e.g., Ø8 for May, 8th)
__ The first letter of YOUR MIDDLE NAME; enter X if you do not know or have a middle name (e.g. M for Mary)
__ The total number of OLDER SIBLINGS you have, including living, deceased, and half (e.g., 0 if you are an only child; enter 9 if you have 10 or more siblings)

- In this example, your identification code would be SEP08M0 (SEPØ8MØ)

The following questions are part of the research data collection, and will not be analyzed until your participation is complete. Feel free to email Jeannie Di Bon (*jeannie@jeanniedibon.com*) if you have questions about the Pilates activities, and would like a response.

Please answer questions 1 and 2 every week.

1. Have you had any increased pain or problems, beyond mild soreness from doing new exercises, that you think is due to the Pilates exercises? Yes / No
    a. If so, briefly describe. [narrative response]
2. Have you had any injuries or increase in symptoms in the past week, unrelated to the Pilates program, that has affected your ability to do the Pilates exercises? Yes / No

If you have increased pain or other symptoms, either due to the Pilates exercises or any other reason, please modify or omit any or all Pilates exercises that do not feel safe to do and contact your health care provider as appropriate.

3. Which of the following are challenges that make it difficult for you to do the Pilates exercises, or to do them as much as you otherwise would? (select all that apply)

    a. I do not enjoy the Pilates exercises
    b. I enjoy different types of exercise more
    c. The Pilates exercises are too uncomfortable
    d. The Pilates exercises are too difficult
    e. Not enough time to exercise, or difficulty scheduling time
    f. Personal issues came up and I was unable to do the exercises
    g. I hurt too much
    h. I am too fatigued to do Pilates
    i. I have symptoms (other than pain or fatigue) that limit my participation (e.g., dizziness, stomach problems, etc.)
    j. I am not physically able to do these exercises now
    k. I am afraid the Pilates exercises might harm me
    l. I am afraid that any type of exercise might harm me
    m. Other: _____

You are invited to answer the remaining questions if you would like to share your thoughts. To keep our research data confidential, please do not include any personal identifying information in your responses.

4. What challenges do you experience in doing the Pilates exercises? These may include challenges with specific exercises, understanding instructions, scheduling time, discomfort, or any other aspect of following this program. [narrative response]
5. How are the exercises and activities in the Pilates course affecting you physically and/or psychologically? [narrative response]
6. What do you enjoy or like most about the Pilates program? [narrative response]
7. What other comments do you have about participating in this on-line Pilates training? [narrative response]

Thank you for participating in this research

Appendix I.1: Email requesting Follow-Up Health History after 8 weeks of Pilates and at 6 month follow-up.

Thank you for participating in "***Assessing the Impact of Internet-Guided Pilates Training on People with Hypermobility.***"

We hope you are continuing to do the Pilates exercises, but remember that you should only do what you feel is appropriate for you. All subjects have access to the Pilates videos during the 8 initial weeks of the study and 6 months of follow up, whether or not you do the Pilates exercises. Subjects who complete the 8 week and 6 month follow-up surveys will also be given permanent access to the on line Pilates modules.

You may contact Jeannie Di Bon if you have questions about the Pilates program, but please do not share information regarding your response to the research questions in SurveyMonkey, as Jeannie is "blinded" to the research data (for scientific validity and to protect your private information, she is not supposed to know how individual subjects respond to the research questions). Please do not Reply to this email. If you would like to contact Jeannie with questions about the Pilates program, please email her directly at: *jeannie@jeanniedibon.com.*

Appendix I.2: Follow-Up Health History after 8 weeks of Pilates and at 6 month follow-up.

__ __ __ The 3 first letters of the month (in English) of your MOTHER'S birthday (e.g., SEP)
__ __ YOUR 2-digit birthday date (e.g., Ø8 for May, 8th)
__ The first letter of YOUR MIDDLE NAME; enter X if you do not know or have a middle name (e.g. M for Mary)
__ The total number of OLDER SIBLINGS you have, including living, deceased, and half (e.g., 0 if you are an only child; enter 9 if you have 10 or more siblings)

- In this example, the identification code would be SEP08M0 (SEPØ8MØ)

Your 7-character ID Code: _____

[Comment: questions will either state "8 weeks" or "6 months" depending on which time the survey is done]

1. Y / N Did your health care program change significantly during the course of this research?
2. Y / N Did you have any increased pain or problems in the past 8 weeks (6 months), beyond mild soreness from doing new exercises, that you think was due to the Pilates exercises?
    a. If so, briefly describe.(narrative)
3. Y / N Did you have any injuries or increase in symptoms during the past 8 weeks (6 months), unrelated to the Pilates program, that has affected your ability to do the Pilates exercises
4. How many total minutes of any Pilates exercises do you currently do in a typical week?____
5. Which of the following reasons explain why you do not do Pilates exercises, or why you do not do them as much as you otherwise would? (select all that apply)
    a. I did not enjoy the Pilates exercises
    b. I enjoy different types of exercise more
    c. The Pilates exercises were too uncomfortable
    d. The Pilates exercises were too difficult
    e. Not enough time to exercise, or difficulty scheduling time
    f. Personal issues came up and I was unable to do the exercises
    g. I hurt too much
    h. I am too fatigued to do Pilates
    i. I have symptoms (other than pain or fatigue) that limit my participation (e.g., dizziness, stomach problems, etc.)
    j. I am not physically able to do these exercises now
    k. I am afraid the Pilates exercises might harm me
    l. I am afraid that any type of exercise might harm me
    m. Other: _____
6. Do you have any comments about reasons why it was difficult or not possible for you to do the Pilates, or any other aspect of following this program. (narrative)
7. Please rate how helpful you feel this Pilates program has been for you, overall: (drag bar)

Not helpful at all 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

8. How have the exercises and activities in the Pilates course affected you physically and/or psychologically (if they have)? (narrative)
9. What did you enjoy or like most about the Pilates program? (narrative)
10. Y / N Would you recommend this Pilates program, ***"Strengthen Your Hypermobile Core"*** to others who are hypermobile?

    Why or why not? (narrative)
11. What other comments do you have about participating in this on-line Pilates training? (narrative)

Thank you for participating in this research