IRB #15452
Revised:

Oregon Health & Science University
RESEARCH PROTOCOL

Protocol Title: Testing and Tuning a Multiparameter Exercise Detection Algorithm

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Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases

BACKGROUND

The risk of hypoglycemia in individuals with type 1 diabetes (T1D) increases considerably during exercise. Increased glucose utilization during exercise as well as promotion of insulin sensitivity, both during and after exercise, have been shown to occur with prolonged periods of increased insulin sensitivity even after a single bout of intense physical activity. As a result, many patients with T1D experience fear of and reluctance to pursue physical activity, in order to avoid the discomforting symptoms associated with hypoglycemia.

The artificial pancreas, a device used for automatic delivery of insulin and glucagon subcutaneously to subjects with T1D, is paving the way to revolutionize the management of this disease. Already, the benefit of improved glycemic control compared to current open-loop pump therapy has been demonstrated in several trials. We have shown that our artificial pancreas (AP) algorithm dual hormone system effectively manages blood glucose in a clinic setting and our group specifically has shown great progress using glucagon to reduce hypoglycemic episodes outside of exercise [1-3]. Our most recent inpatient study, as yet unpublished, shows that adjusting insulin and glucagon delivery during closed loop treatment, after announcing exercise, effectively reduces mean time below a glucose level of 70 mg/dl when compared to closed loop control without adjustments. We utilized initial open-loop data from this study to help devise dosing changes for the AP algorithm [4].

In order to prepare for a future home study, the ability to detect, grade, and classify physical activity so as to appropriately adjust system parameters is vital in helping to prevent exercise-induced hypoglycemia in the home setting. Currently, our closed-loop system transmits heart rate and accelerometry outputs from a Zephyrlife BioPatch monitoring device to a Nexus 5 smart phone master controller via Bluetooth. The algorithm then converts the heart rate and accelerometry data into modified estimated energy expenditure - accounting for age, weight, height, sex, resting and sitting heart rates - to determine if exercise is present. However, further data collection is needed to hone the specificity and sensitivity of the detection algorithm to account for a wide variety of subject characteristics and activities.

This study is designed to collect 3-axis accelerometry data and heart rate data during a variety of different home activities, as well as during formal exercise in both healthy subjects and subjects with type 1 diabetes and optionally VO_2 data from a portable VO_2 mask. The data collected will be used to further enhance our algorithm that, in future closed-loop studies, will detect exercise

and automatically trigger algorithmic adjustments to reduce exercise-related hypoglycemia during and after exercise in individuals with T1D.

SPECIFIC OBJECTIVES

Primary Objective: To obtain accelerometer, heart rate, and optionally VO_2 data from subjects with and without T1D during various home related activities and formal exercise for the purpose of training an exercise detection algorithm.

Secondary Objective: To obtain data from insulin pumps and glucose sensors from subjects with T1D during open-loop therapy while exercising to further define changes in glucose level while performing home activities and formal exercise.

HYPOTHESIS

We hypothesize that an exercise detection algorithm that utilizes accelerometer and heart rate data along with patient parameters, such as age, sex, weight, height, sitting and resting heart rate, can accurately and reliably estimate energy expenditure. We also hypothesize that certain home exercises may be of sufficient intensity to trigger a fall in glucose levels, which would require dose adjustment during closed-loop treatment of T1D in order to prevent hypoglycemia.

ENDPOINTS:

Primary Endpoints: The primary endpoints are accelerometer and heart rate data from both healthy subjects and subjects with T1D and healthy subjects during home activities and a structured exercise period.

Secondary Endpoints: Secondary endpoints include glucose data from Dexcom continuous glucose monitoring (CGM) systems and insulin pumps attached to subjects with T1D during home activities and formal exercise.

STUDY TYPE: Pilot study for data collection.

STUDY POPULATION

The study population will include healthy adults and adults with T1D who have been using an insulin pump for at least 6 months, ages 21 – 45 years of age. Older subjects are excluded due to higher risk of unrecognized coronary artery disease. Younger subjects are excluded as it is appropriate to assess safety first in the adult population and the current AP system has not been tested in the younger population. Use of an insulin pump is required so as to obtain accurate insulin dosing information on subjects with T1D.

Type 1 Diabetic Subject Criteria

Inclusion criteria:

Subjects meeting all of the following criteria will be considered for enrollment into the study:

a. Male or female subjects 21 to 45 years of age with a diagnosis of T1D for at least 6 months on an insulin pump.
b. Physically active on a regular basis, i.e. at least 3 days of scheduled physical activity per week and willing to perform approximately 60 minutes of exercise (as determined by the investigator after reviewing the subjects activity level).

c. Willingness to follow all study procedures.
d. Willingness to sign informed consent and HIPAA documents.

Exclusion criteria:
Subjects presenting with any of the following will not be considered for enrollment in the study:

a. Pregnancy or Lactation:
    i. For women of childbearing potential, there is a requirement for a negative urine pregnancy test.
b. Any cardiovascular disease, defined as a clinically significant EKG abnormality at the time of screening or any history of: stroke, heart failure, myocardial infarction, angina pectoris, or coronary arterial bypass graft or angioplasty. Diagnosis of 2nd or 3rd degree heart block or any non-physiological arrhythmia judged by the investigator to be exclusionary.
c. Renal insufficiency (GFR < 60 ml/min, using the MDRD equation as report by the OHSU laboratory).
d. Hematocrit of less than or equal to 34%.
e. History of severe hypoglycemia during the past 12 months prior to screening visit or hypoglycemia unawareness as judged by the investigator.
f. Adrenal insufficiency.
g. Any active infection.
h. Known or suspected abuse of alcohol, narcotics, or illicit drugs (except marijuana use).
i. Seizure disorder.
j. Active foot ulceration.
k. Severe peripheral arterial disease characterized by ischemic rest pain or severe claudication.
l. Major surgical operation within 30 days prior to screening.
m. Use of an investigational drug within 30 days prior to screening.
n. Chronic usage of any immunosuppressive medication (such as cyclosporine, azathioprine, sirolimus, or tacrolimus).
o. Bleeding disorder, treatment with warfarin, or platelet count below 50,000.
p. Current administration of oral or parenteral corticosteroids.
q. Any life threatening disease, including malignant neoplasms and medical history of malignant neoplasms within the past 5 years prior to screening (except basal and squamous cell skin cancer).
r. Any concurrent illness, other than diabetes, that is not controlled by a stable therapeutic regimen.
s. Beta blockers or non-dihydropyridine calcium channel blockers.
t. A positive response to any of the questions from the Physical Activity Readiness Questionnaire, see Appendix A.
u. Any chest discomfort with physical activity, including pain or pressure, or other types of discomfort.
v. Any clinically significant disease or disorder which in the opinion of the Investigator may jeopardize the subject's safety or compliance with the protocol.

Healthy Subject Criteria
Inclusion Criteria:

a. Male or female subjects 21 to 45 years of age.
b. Physically active on a regular basis, i.e. at least 3 days of scheduled physical activity per week and willing to perform approximately 60 minutes of exercise (as determined by the investigator after reviewing the subjects activity level).
c. Willingness to follow all study procedures.
d. Willingness to sign informed consent and HIPAA documents.

Exclusion criteria:

a. Pregnancy or Lactation:
    a. For women of childbearing potential, there is a requirement for a negative urine pregnancy test.
b. Any history or evidence of renal insufficiency, adrenal insufficiency, liver disease or anemia.
c. A history of cerebrovascular disease or coronary artery disease (or angina) regardless of the time since occurrence.
d. Congestive heart failure, New York Heart Association (NYHA) any class.
e. Diagnosis of 1st, 2nd or 3rd degree heart block or any arrhythmia judged by the investigator to be exclusionary.
f. Any condition which, in the opinion of the investigator, makes it difficult to engage in vigorous physical activity.
g. Any active infection.
h. Severe peripheral arterial disease characterized by ischemic rest pain or severe claudication.
i. Active alcohol abuse, substance abuse, or severe mental illness (as judged by the principal investigator).
j. Active malignancy, except basal cell or squamous cell skin cancers.
k. Major surgical operation within 30 days prior to screening.
l. Seizure disorder.
m. Bleeding disorder, or treatment with warfarin.
n. Use of an investigational drug within 30 days prior to screening.
o. A positive response to any of the questions from the Physical Activity Readiness Questionnaire.
p. Any chest discomfort with physical activity, including pain, pressure or other types of discomfort.
q. Any reason the principal investigator deems exclusionary.

STUDY RECRUITMENT

Subjects will be recruited from OHSU clinics, from flyers to be posted in approved places at OHSU, or from the OHSU Subject Recruitment website. Records from OHSU Harold Schnitzer Diabetes Clinic patients may be screened to find potential TID subjects. Subjects will also be recruited from a list of subjects who participated in past OHSU studies, past studies involving Drs. Castle or El Youssef, from the OHSU diabetes research registry and www.clinicaltrials.gov. Up to 60 subjects may be screened in this study with up to 40 subjects enrolled into the study at OHSU, split 60-80% healthy subjects and 20-40% subjects with T1D.

Non-English speaking T1D subjects will not be recruited since this protocol will require use of a device and mobile software (Dexcom G4, Dexcom Share or Dexcom G5 Mobile) that does not have non-English versions available yet for users.

Withdrawal Criteria
The subject may withdraw at will at any time or at the discretion of the Investigator.

A subject must be withdrawn if the following applies:

1. Hypoglycemia, in T1D subjects, during the treatment period posing a safety problem as judged by the investigator.
2. Hyperglycemia, in T1D subjects, during the treatment period posing a safety problem as judged by the investigator.
3. Protocol deviation having influence on efficacy or safety data as judged by the Investigator.
4. Substantial and repeated non-compliance with trial procedures.
5. Pregnancy.
6. Intention of becoming pregnant.

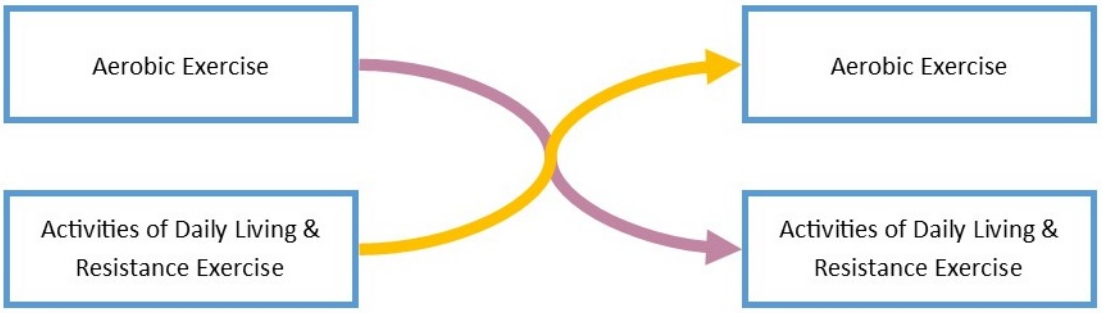
OVERALL STUDY DESIGN
The aim of the study is to determine if accelerometer, heart rate, and VO_2 data can be utilized to enhance our exercise detection algorithm for use in our closed-loop system. The VO_2 mask may be worn by subjects during a single exercise visit to determine the actual energy expenditure of each activity using metabolic equivalents (METs). Each subject may wear one or more monitoring devices which will be transmitting heart rate and accelerometer data to a master controller, such as a Nexus 5 smart phone. The master controller may be running an algorithm to detect and grade exercise, and will be collecting data for offline analysis and algorithm tuning. This device **will not** be connected to a glucose sensor, a pump delivering insulin or a pump delivering glucagon for the purpose of managing blood sugar in subjects with T1D.

STUDY DETAILS
Visit 1: Screening

Screening will take place at OHSU's Harold Schnitzer Diabetes Health Center clinic Prior to any procedures, the consent/authorization form will be reviewed and signed, with a copy of the consent/authorization form given to the subject. The original will be kept for the source document. This visit will take approximately 1.5 hours for healthy subjects.
In all subjects, study personnel will review medical history and medications, and fill out the Physical Activity Readiness Questionnaire (Appendix A); height, weight, pulse, blood pressure, and a resting EKG will be obtained; a study investigator will perform a physical examination, excluding breast and pelvic exams; and females of child-bearing potential will take a urine pregnancy test, which must be negative to participate. A study investigator will assess inclusion/exclusion criteria and review the subject's medical record for clarification as needed. Subjects may be asked to be fitted with a portable VO_2 mask and will wear the mask for approximately 1 hour to obtain accurate baseline data. Subjects will be asked to abstain from food, caffeine and alcohol for approximately 3-4 hours prior to screening to ensure accurate VO_2 baseline data. A three digit subject ID number will be assigned to each subject. The TID subjects

and the healthy subjects will be randomized separately to ensure that there are equal numbers within each arm of the study, as follows:

1) Aerobic exercise at OCTRI followed by activities of daily living and resistance exercise at the POC lab, or
2) Activities of daily living and resistance exercise at the POC lab followed by aerobic exercise at OCTRI



This randomization is intended to help address if glucose changes in subjects with T1D are affected by either the order of structured exercise and activities of daily living (ADLs) or aerobic vs. resistance exercises.

T1D Subject Screening Specifics: This screening will take approximately 2 hours. At the beginning of screening, after consent has been signed, subjects with T1D will be asked to test their blood sugar using their own meter and strips. Venous blood samples will be taken for complete blood count, and complete metabolic panel (including creatinine, liver panel, and electrolytes) labs. If subjects have had the aforementioned labs performed within the 3 months prior to the intended date of Visit 2 and we can access the results, venous blood samples will not be taken. These subjects will be fitted with a Dexcom G4,Share, or Dexcom G5 Mobile glucose sensor and short device training will be performed at the screening. The subjects that require blood tests will be asked to return for an approximately 15-30 minutes sensor training and insertion visit if their lab results determine that they pass screening.

Visit 2: Exercise Study

For all subjects, the exercise visit will occur within 12 weeks of screening. For T1D subjects, the exercise visit will occur no less than 24 hours and no more than 5 days from the time of sensor insertion.

Subjects with T1D will always be asked to check their capillary blood glucose (CBG) before driving to the clinic and to bring a snack in the car in case hypoglycemia does occur (in which case, subjects must park and treat the hypoglycemia).

This visit will take approximately 4 hours and take place at the OCTRI Clinical research unit as well as the Biomedical Engineering Point of Care (BME POC) Lab. A study technician and

investigator will always be present in the room throughout the study for safety purposes. On the day of the study, subjects will be instructed to have breakfast at 6 am.

Subjects will be instructed to arrive at OCTRI or BME POC lab around 8 am depending on their randomization group. Subjects with T1D will measure their capillary blood glucose (CBG) with their own glucose meter at the beginning of the visit. Subjects with T1D will continue their normal basal insulin delivery using their own pump and will be allowed to adjust insulin delivery during the structured exercise period as they normally would at home. All subjects will be fitted with a device to record accelerometer and heart rate data, and may be fitted with the portable VO_2 mask.

During the aerobic exercise period and resistance exercise period, there will be defined rules for stopping, including:

1) If the subject feels unwell,
2) If a subject with T1D develops hypoglycemic symptoms, such as excessive sweating, shaking/tremors, palpitations, feelings of dread or panic, light-headedness, nausea, difficulty concentrating or the like,
3) If the subject develops chest pain/pressure,
4) If the subject develops undue shortness of breath,
5) If the maximum heart rate (defined as 220 – the subject's age) is reached or exceeded,
6) For patient preference.

The study technician and physician will accompany the subject up and down the tram between the two portions of the visit (from OCTRI to CHH or CHH to OCTRI).

Aerobic Exercise: During the aerobic exercise event, all subjects will perform exercise on a treadmill or cycle ergometer in three 15 minute periods each with at least 10 minutes of rest between each exercise period. Exercise intensity will vary between periods to achieve different energy expenditures, which may be determined based on VO2 measurements. Subjects with T1D will do a CBG prior to exercise and will not start exercising if glucose is <70 mg/dl; they will be given 15-20 grams of carbohydrates for CBG values of <70 mg/dL and CBG retested in 15 minutes. A code cart is on site at OCTRI and a code team is available by page at all times. After completion of the exercise, T1D subjects will complete another CBG sample and have it reviewed by an investigator. These subjects will be provided with a snack after testing if necessary to avoid post-testing hypoglycemia.

ADL and Resistance Exercise: T1D subjects will complete a CBG prior to starting this exercise period if ADL and resistance exercise is their first exercise of Visit 2. If the T1D subject has just come from aerobic exercise, they will not need to complete a CBG prior to starting this period.

Activities simulating normal household activities will be completed in the Point of Care Lab. These activities may include:

1) sitting on a chair or lying on a bed,
2) washing dishes or folding laundry,
3) sweeping the floor or vacuuming,
4) organizing a room or adjusting furniture in a room,

5) scrubbing the carpet or the walls and/or
6) going up and down flights of stairs.

Each activity will be performed between 5-15 minutes. After the ADL are complete, subjects will perform resistance exercises such as straight-leg raises or wall sits for approximately 20 minutes. All items necessary for performing these activities are provided in the POC lab, and subject safety throughout all activities will be ensured by coordinator observation. A CBG will be completed at the end of this exercise portion if the subject has already completed aerobic exercise. If the subject has yet to complete the aerobic portion of the visit, they will not take a CBG measurement at this time and will instead complete one just prior to starting aerobic exercise.

After the study is completed, the subject will have all devices removed. Subjects with T1D will have a CBG sample taken and reviewed by an investigator. If necessary, oral carbohydrates will be given for values below 70 mg/dl, and an insulin bolus will be given if deemed appropriate by the study investigator for values above 250 mg/dl. Study staff will download the data from the subject's personal insulin pump.

Visit 3: Study Follow-up

The study follow-up visit will be conducted by phone call to the subject at the phone number obtained during screening, to determine the general post-discharge status of the subject. The subject will be contacted 48 hours (+/- 24 hours) after the exercise portion of the study takes place.

CONFIDENTIALITY AND PROTECTION OF HUMAN SUBJECTS

Risks and Benefits:

Risks: The risks of the protocol procedures are considered minor. It should be noted that a fully trained physician will be in constant attendance on the research ward. The likelihood of significant harm is quite low. Risks of exercise include falls, sprains, bruises, very low risk of bone fractures and head trauma.

In subjects with T1D, there is a small risk of sensor fracture, and in such a case, a piece of the sensor could be left in the tissue after sensor removal. For this reason, the study investigator will inspect each removed sensor for the possibility of breakage or fracture. Any evidence of sensor breakage will be recorded and reported to FDA and the sensor company.

Benefits: The subject may not directly benefit from being in this study; however, their participation may help to advance automated insulin and glucagon delivery technology.

Monitoring Entity:

This investigation will be monitored by the principal investigator Joseph El Youssef, MD. Dr. El Youssef has no commercial interest in any of the companies which manufacture any of the devices used in this study.

Data Collection:

Subject privacy will be protected by using a three digit identifying number to code study documents. Study staff will record data required by the protocol onto the Case Report Forms (CRF). Case report forms (CRF) for this study will be entered into REDCAP, a clinical research electronic data repository housed at Oregon Health Science University and administered by the Oregon Clinical and Translation Research Institute (OCTRI). Investigators and research coordinator will verify that the procedures are conducted according to the approved protocol. All paper source documents will be kept in a locked cabinet for a minimum of five years. Original, completed CRF's will be kept with the PI in a designated repository. All data from CRF's will subsequently be entered into the authorized electronic REDCAP database

Recording of Data:
Investigators and staff will record data collected during the clinical trial on the CRF's. Case report forms (CRF) for this study will be entered into REDCAP, a clinical research electronic data repository housed at Oregon Health Science University and administered by the Oregon Clinical and Translation Research Institute (OCTRI). The REDCAP CRFs will include:

1. Screening form
2. Exercise Study form
3. Phone Update Form
4. Adverse Event form
5. Serious Adverse Event form
6. Concomitant Medications

The Principal Investigator may authorize other personnel to make entries in the CRF.

Data Analysis:
All data will be actively streamed to the master controller on the Nexus 5 phone and will be analyzed online with a currently described exercise detection algorithm [5]. The algorithm results will be compared to data from the VO2 mask in order to assess the sensitivity and specificity of the algorithm, and may also be used to improve upon the parameters of the algorithm. Additionally, glucose data from CGM devices will be analyzed for the rate of change of glucose (in mg/dl/min) during exercise events in order to help quantify this for different activities. Model analysis with a published non-linear model of glucose regulation [6] will help track glucose changes with respect to insulin delivered and activity level.

Monitoring Procedures:
This protocol is written in accordance with the principles established by the 18th World Medical Assembly General Assembly (Helsinki, 1964) and amendments and clarifications adopted by the 29th (Tokyo, 1975), 35th (Venice, 1983), 41st (Hong Kong, 1989), 48th (Somerset West, South Africa, 1996), 52nd (Edinburgh, 2000), 53rd (Washington, 2002), 55th (Tokyo, 2004), and 59th (Seoul, 2008) General Assemblies. The investigator will ensure that the study described in this protocol is conducted in full conformance with those principles, the protocol, current FDA regulations, ICH Good Clinical Practices (GCP) guidelines, Good Laboratory Practices (GLP) guidelines, local ethical and regulatory requirements, including the Federal Food, Drug and Cosmetic Act, U.S. applicable Code of Federal Regulations (title 21), any IEC requirements relative to clinical studies.

Should a conflict arise, the investigator will follow whichever law or guideline affords the greater protection to the individual subject. The investigator will also ensure thorough familiarity with the appropriate use and potential risks of use of all study devices as described in this protocol, prior to the initiation of the study.

Unanticipated problems will be detected by reviewing descriptions of known or foreseeable adverse events and risks in the IRB-approved research protocol and the current IRB approved consent form, any underlying disease or conditions of the subject experiencing the adverse event, a careful assessment of whether the adverse event is related or possibly related to the subject's participation in the study. Triggers for reporting unanticipated problems are seizure, hospitalization, death or any other occurrence considered serious by the PI.

Any adverse event and/or unanticipated problem (UP) will be reported to the investigator monitor immediately by one of the investigators. One of the investigators will always be on-site during the studies and will write up a description of the adverse event/unanticipated problem. Deaths and potentially life-threatening events will be reported to the IRB within seven calendar days after the PI learns of the event. All other UPs must be reported to the IRB within fifteen calendar days. The report will be submitted to the IRB by the principal investigator or study coordinator. All summary of all UP's and adverse events will be submitted with the continuing review.

Confidentiality Procedures:
To protect confidentiality, standard institutional practices will be followed as described in the OHSU Information Security and Research Data Resource Guide (http://ozone.ohsu.edu/cc/sec/isg/res_sec.pdf) to maintain the confidentiality and security of data collected in this study. Study staff will be trained with regard to these procedures. Upon enrollment, subjects will be assigned with a three-digit code that will be used instead of their name, medical record number or other personally identifying information. The key associating the code and the subject's personal identifying information will be restricted to the PI and study staff. The key will be kept secure on a restricted OHSU network drive in a limited access folder.

Electronic files for data analysis will contain only the subject code. Access to data/specimens is restricted to study personnel and requires OHSU ID/password authentication. Paper files will be stored in locked filing cabinets in restricted access offices at OHSU. Electronic data is stored on restricted drives on the OHSU network or stored on encrypted computers as well as on the web-accessible REDCap database housed on an OHSU secure server. User passwords will be changed every 3 months and a firewall will be enabled at all times. After the study, source documents will be maintained at the participating clinical center (or offsite record storage facilities) 2 years after a marketing application is approved for our group's artificial pancreas/decision support device since the data from this study will be included in future software revisions or discontinuance of pursuit of marketing approval. At the end of the study, an electronic copy of the database will be provided on a CD for long-term storage under lock.

APPENDIX A

Physical Activity Readiness Questionnaire (PAR-Q) and You

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly:

YES	NO		
☐	☐	1.	Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
☐	☐	2.	Do you feel pain in your chest when you do physical activity?
☐	☐	3.	In the past month, have you had chest pain when you were not doing physical activity?
☐	☐	4.	Do you lose your balance because of dizziness or do you ever lose consciousness?
☐	☐	5.	Do you have a bone or joint problem that could be made worse by a change in your physical activity?
☐	☐	6.	Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
☐	☐	7.	Do you know of any other reason why you should not do physical activity?

If you answered:

YES to one or more questions

Talk to your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want – as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- Start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go.
- Take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively.

Delay becoming much more active:

- If you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or
- If you are or may be pregnant – talk to your doctor before you start becoming more active.

Please note: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed use of the PAR-Q: Reprinted from ACSM's Health/Fitness Facility Standards and Guidelines, 1997 by American College of Sports Medicine

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