University of Pittsburgh

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TITLE: Use of Dynamic Arm Supports to Promote Activities of Daily Living for Individuals with DMD

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STUDY PROTOCOL

Brief description

This project seeks to explore the benefits of dynamic arm supports in non-ambulatory individuals with Duchenne muscular dystrophy (DMD) with upper extremity weakness (n=24 to 30). This study is a longitudinal, randomized control trial evaluating the use of two upper extremity (UE) support devices (KINOVA O540 and JAECO WREX). Following installation and training, eligible participants will complete a four week in-home trial using one of the devices. The ActiGraph, a wrist worn activity monitoring device, will be worn during a two-week baseline period, during the device trial, and an additional two-week period following the device trial to capture UE movement patterns. UE performance will be further quantified with use of a physical motor assessment, the Performance of Upper Limb Scale Assessment and patient reported outcomes. Data gleaned will provide important knowledge and objective results regarding the potential benefit of dynamic arm supports in individuals with DMD with limited functional use of their upper extremities.

Recruitment

Individuals with DMD will be recruited through national and local disability related organizations, including the Muscular Dystrophy Association and DuchenneConnect. MDA and DuchenneConnect may email the parents of children with DMD registered with the organization. Approved recruitment materials will be provided for these organizations to share with consumers via mailings, in-person, website and/or social media. Potential participants recruited through the UPMC and/or Children's Hospital Systems will be approached by their treating clinician. If interested in learning more about the opportunity, they will be provided with an approved recruitment flyer to contact the study coordinator. No recruitment materials will be used without prior approval. The flyer instructs potential subjects to contact a clinical coordinator for additional information.

Study Aims

The objective of this proposal is to explore the benefits of dynamic arm supports in non-ambulatory individuals with Duchenne muscular dystrophy (DMD) with upper extremity weakness. This study is a randomized control trial evaluating the use of and comparing the differences between two dynamic arm supports: the KINOVA O540 (powered/actively actuated) and the JAECO WREX (non-powered/passive) in the natural environment. Both devices are minimal risk devices that are commercially available products.

Specific Aims:

1. Explore the use of both passive and actively actuated dynamic arm supports in individuals with DMD with upper extremity weakness.
    1a. Compare upper extremity movement patterns (i.e. accelerometer, gyroscope) with use of the ActiGraph GT9X activity monitor before, during and after use of a dynamic arm support.
    1b. Compare differences between passive and actively actuated dynamic arm supports in individuals with DMD with upper extremity weakness within a longitudinal and randomized control trial.

2. Explore the everyday life experiences of individuals with DMD with upper extremity weakness and the impact a dynamic arm support may have in increasing independence and quality of life.
    2a. Identify meaningful individualized goals with use of a dynamic arm support.
    2b. Compare upper extremity function before, during, and after use of a dynamic arm support.

Inclusion and exclusion criteria

Participants are included if they are:

1) 14 years of age or older
2) Self-report diagnosis of Duchenne muscular dystrophy (DMD)
3) Use a wheelchair for mobility
4) Score 0-4 on the entry item of the Performance of the Upper Limb test.
5) Self-report of needs assistance/unable to achieve independently on at least 10 items on the UL ADL self-report questionnaire
6) Able to follow instructions
7) Informed consent provided by self (18 and over) or by parent or legal guardian (if under the age of 18)

Participants are excluded if:

1) They do not have minimum level of UE function to operate the assigned dynamic arm support (Score of 5-6 on the entry item of the Performance of the Upper Limb test or any other impairment limiting use)
2) The assigned dynamic arm support is unable to be mounted to wheelchair (mounts will vary based on manufacturer/model of wheelchair
3) They have a medical or psychological diagnoses (unrelated to muscular dystrophy) that would impact participation in daily activities or routines as reported by caregiver.

Sample Size and Power Analysis

There is limited research available on the use of dynamic arm supports and no prior literature using this type of portable fitness tracking device to measure upper extremity function in boys with Duchenne. This sample size was determined from the feasibility of recruitment in this rare disease population, the anticipated rate of attrition, and the minimal detectable effect size for the planned analyses. The goal of our analyses will be to examine and record effect sizes used to power larger, more confirmatory studies of powered arm support devices. With 30 participants completing the study, we will be able to detect a small effect (f =0.22) with 80% power when testing within subject change, and an effect (f =0.28) with 80% power when testing between subject change, in a repeated measures model using a two-tailed F test and a significance level of 0.05.

Study Procedure

The total duration of research activities per participant is 8 weeks, may be scheduled across a total of 20 weeks. This 8-week period includes a 2-week baseline data collection period, a 4-week device home trial, and a 2-week follow up data collection period. The study includes at least two in person study visits with research personnel in the home environment.

Participants are randomized to the use of one of the two dynamic arm supports being evaluated to use during the home trial: the JAECO WREX or the Kinova O540. Participants will complete testing with the arm support device that they are randomized to and then use this device for 4 weeks. Participants are asked to use the device at least 2 hours a day and practice the determined goal areas. Participants were also asked to wear an ActiGraph, a wrist worn commercially available portable fitness tracking device, throughout all periods of the study on the wrist of the arm using the dynamic arm support.

Baseline (2 weeks)

ActiGraph

1) The ActiGraph to be worn on the participant's wrist throughout the study to capture UE movement patterns and provide information about daily activities. Data are download regularly using an application to sync the ActiGraph with a secure cloud.

Installation Visit and Training- Home Visit 1

Research personnel install the dynamic arm support device on the participant's wheelchair at the participant's home or an agreed upon location. Caregivers will be trained on the use and removal of the device. Testing will be completed with and without the device. The participant will wear the ActiGraph during this visit. Videotaping will take place, with the participant's written consent, during goal area and testing. Assessments include:

1) Specific goal area practice and evaluation (Goal Attainment Scale)
2) Performance of the Upper Limb test
3) Range of motion
4) Upper extremity Activities of Daily Living Questionnaire
5) Quality of life, fatigue, and social participation questionnaires

Device Trial (4 weeks)

The participant will use the dynamic arm support for at least 2 hours during the day throughout the 4-week trial. The participants are instructed to practice their individual goal areas with the device. Participants will continue to wear the actigraph during the day and night and document the hours the device was used along with a brief description of the activities involved. The research team will be in regular contact with you/your son and additional phone calls, video chats, or in person visits will be scheduled as needed.

Home Visit 2

After completion of the 4-week home trial, research personnel will meet with the participant at their home or at an agreed upon location to complete testing and removal of the device from the participant's wheelchair. The participant will wear the ActiGraph during this visit. Videotaping will take place, with the participant's written consent, during goal area and testing. Assessments include:

1) Specific goal area practice and evaluation (Goal Attainment Scale)
2) Performance of the Upper Limb test
3) Range of motion
4) Upper extremity Activities of Daily Living Questionnaire
5) Quality of life, fatigue, and social participation questionnaires

Follow up Data Collection (2 weeks)

For an additional 2-week period, participants will continue to follow the same ActiGraph procedures and complete the weekly activity log as described in the baseline and device trial procedures. Upon completion of the follow-up portion of the study, the participant and their caregiver will be asked to participate in a follow up interview to obtain feedback related to experiences with the dynamic arm support and ActiGraph.