Effects of vibration on chronic leg edema in chair-bound older adults: A randomized pilot trial

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Abstract

Background

Elderly individuals can easily develop leg edema that can become chronic, which may result in various problems. Therefore, appropriate care for the edema should be provided. In some cases, chronic leg edema among elderly individuals cannot be controlled by the standard care such as leg elevation or compression. A previous study reported that vibration benefited upper limb lymphedema; however, its effects on chronic leg edema are not yet clarified. Therefore, this study aimed to clarify the effects of vibration for reducing chronic leg edema among chair-bound elderly individuals.

Methods

For participant allocation, a computer-generated list of random numbers was used. Nursing home residents aged ≥65 years with chronic leg edema who spent more time sitting than standing or lying during the day were randomly assigned to the intervention (n = 7) or control group (n = 7). The intervention group underwent vibration therapy three times a day for 2 weeks at 47 Hz and 1.78 m/s^2 frequency and horizontal vibration acceleration, respectively. The pitting test was performed at 22 sites, and participants' pitting scores were calculated based on the pitting depth. Pitting score changes at pre- and post-intervention were compared between the intervention and control groups. Both participants and investigators were not blinded to group assignment.

Results

The median age of the intervention and control groups was 86 and 84 years, respectively. Participants' characteristics and edema severity at baseline were not significantly different. The median total pitting score change in the intervention group was −0.4 (interquartile range: −5.3–1.8), which was significantly lower than that of the control group (2.0 [interquartile range: 1.0–5.3], $P = 0.01$). The intervention group was more likely to have controlled edema (64.3%) than the control group (21.4%) (χ^2 (1) = 5.25, $P = 0.02$).

Conclusions

The intervention group was more likely to have controlled edema than the control group, suggesting that vibration could prevent the worsening of chronic leg edema in chair-bound elderly individuals.

Trial registration: UMIN Clinical Trials Registry, UMIN000017716. Registered 1 July 2015, https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000020522

Background

Edema is caused by various kinds of diseases, such as heart, kidney, liver, thyroid, and lymphatic diseases.[1] Besides, leg edema sometimes occurs following long periods of sitting or standing among healthy persons, which can be effectively reduced by lying or calf muscle pumping through contracts

during leg movement.[2] However, elderly individuals can easily develop leg edema that can become chronic due to long hours of sitting each day, along with cardiovascular dysfunction, decreased lower limb muscle strength, skin tension, and nutritional conditions attributable to aging.[1]

Previous studies have investigated the prevalence of leg edema in elderly patients. They showed that 5.4% of elderly individuals have edema,[3] and 48% of inpatients in a geriatric ward (n = 64) had peripheral edema.[1] One study found that 92% of elderly individuals who sit for >12 h had leg edema (n = 36).[4] These reports suggested that many elderly individuals who sit for long periods may experience leg edema. Moreover, >59.0% of elderly individuals are reported to have uncontrolled edema[3]; among them, >50% remain untreated.[1] These reports indicate that edema among elderly individuals is not appropriately treated.

Elderly patients experience various problems associated with chronic leg edema. Leg edema causes feelings of weariness and heaviness[5] and decreased activity during daily living. Moreover, it increases the risk for falls caused by decreased ankle movement range.[6] Edematous skin is also easily damaged and prone to pressure injuries[7] and skin tears.[8] Therefore, chronic leg edema might greatly affect the quality of life (QOL) of elderly individuals. Given these problems, appropriate care must be provided to reduce chronic leg edema and maintain QOL for elderly individuals.

Two problems occur when providing care to elderly patients with leg edema. First, providing continuous care to reduce edema is difficult because the most current care methods require manpower. Due to the absence of guidelines for the treatment of leg edema among elderly individuals, nurses have considered various care methods. For example, leg elevation exercises[9] and typical treatments such as foot baths and massages are performed. However, these methods require manpower. Second, the use of compression therapy, the standard care method for the treatment of lymphoedema or venous edema,[10] might limited in elderly individuals due to the following reasons: high prevalence of arterial blood flow insufficiency[11, 12, 13] and the presence of vulnerable skin. Vulnerable skin can easily be injured if the stockings are inappropriately worn, as elderly individuals often have difficulty wearing compression stockings.[14]

Therefore, this study focused on vibration therapy as care methods using devices may reduce the need for additional manpower. Previous experiments showed that vibration effectively reduced upper limb lymphedema when provided as an additional care for simple lymphatic drainage[15] and improved lower limb transcutaneous oxygen tension during hemodialysis.[16] Furthermore, vibration improved the leg fluid flow among perimenopausal women[17] and can reduce the leg edema in healthy adults.[18] However, the effects of vibration therapy on chronic leg edema in chair-bound elderly individuals remain unclear.

The present study aimed to clarify the effects of vibration therapy to reduce chronic leg edema in chair-bound elderly individuals. Our hypothesis was that edema severity in the intervention group would be more improved than that in the control group.

Methods

Study design and population

This study used a randomized controlled, non-blinded, parallel comparison design and adhered to CONSORT guidelines. (UMIN-CTR trial registration number: UMIN000017716). For participant allocation, a permuted block (4 persons/block) randomization method was used to ensure balanced assignments. A computer-generated list of random numbers was used. The allocation ratio was 1:1. The research assistant generated the random allocation sequence, enrolled participants, and assigned participants to interventions. The study was conducted from August to November 2015 at a nursing home in Kanazawa City, Japan.

Participants were nursing home residents with chronic leg edema. Chronic edema was defined as subcutaneous tissue swelling that continued for ≥3 months based on a previous study.[19] Inclusion criteria were nursing home residents aged ≥65 years and those who spent more time sitting than standing or lying during the day. Exclusion criteria were residents diagnosed with aneurysm or thrombosis, those who were not diagnosed with chronic leg edema, those who were otherwise considered unsuitable by a physician or nurse, or those who could not provide consent.

Pitting depth is classified into the following: 0 to 4: 0 = 0 mm; 1+ = 0 – 1.9 mm; 2+ = 2 – 3.9 mm; 3+ = 4 – 5.9 mm; and 4+ = ≥6 mm depending on the physical examination method.[20] Participants classified as having chronic leg edema were those with pitting depth of ≥1+ severe edema on at least one site of their legs.

Intervention

The intervention group underwent vibration therapy for 2 weeks. The size of the vibration device (Rela feel, Global-Micronics Co., Ltd. Kashiwa, Japan) was 616 × 182 × 114 mm (length × width × height). The frequency and horizontal vibration acceleration were set at 47 Hz and 1.78 m/s^2, respectively, as per the permissible range for the minimum health and safety requirements.[21] Previous studies reported that this device can be safely used for elderly individuals.[22] The vibrator was placed under the legs with cushions between them (Figure 1). Vibrations were performed three times: morning (06:00–09:30), day (12:30–14:30), night (18:00–21:00), and each vibration was performed for 15 min. During the morning and daytime vibration therapy sessions, participants were either sitting or lying down depending on their lifestyle. At night, patients were lying down. The control group received no intervention, including leg vibration or elevation.

Outcome measurements

The primary outcome was pitting score. Secondary outcomes were leg volume and subcutaneous echo-free space grade (SEF) evaluated using ultrasound (US) images. We evaluated all measurement items before and after intervention period.

Pitting scores were calculated using the pitting test results. The pitting test was performed as described in a previous study.[23] The investigator applied an even amount of pressure on the measuring site with the right thumb for 10 s. All measurements were provided by one researcher, and the intra-rater reliability (1, 1) of the pressure was 0.923. Measurements were taken at 22 sites in the right and left lower extremities. Pitting depths were converted to pitting scores: pitting 0, 0 point; pitting 1+, 1 point; pitting 2+, 2 points; pitting 3+, 3 points; and pitting 4+, 4 points. The points were added to obtain a total score for each leg.

The leg volume was determined using the following formula to calculate the truncated cone volume.[24] $V = V_1 + V_2$, $V_1 = 1/3\pi h\ (r_1r_1+r_1r_2+r_2r_2)$, and $V_2 = 1/3\pi h\ (r_2r_2+r_2r_3+r_3r_3)$, where V_1 represents the volume of the ankle to distal leg; V_2 represents the volume of the distal to proximal leg; r_1 is the ankle radius, r_2 is the distal leg radius, and r_3 is the proximal leg radius; and h is the leg length (one-third of the length of the lateral ankle to the fibular head apex).

SEF is a qualitative analysis method to analyze US images. The principal researcher obtained all US images at 10 sites on the right and left lower extremities. The dorsalis pedis was a short-axis image, whereas the remainder was long-axis images. A US console (Noblus, Hitachi Aloka Medical, Ltd., Mitaka, Japan) and linear transducer (L64, frequency range: 5–18 MHz) with identical settings were used: gain, 15; dynamic range, 70 dB; and focus point, 0.5 cm. SEF was classified into the SEF in five grades: 0, 1, 2-type A, 2-type B, and 2-type C using a modified method described by Suehiro et al.[25] (Figure 2). Leg images were classified by the principal researcher and another researcher with experienced in analyzing US images of leg edema. SEF values were converted to SEF scores: grade 0, 0 point; grade 1, 1 point; grade 2-type A, 2 points; grade 2-type B, 3 points; and grade 2-type C, 4 points. The points were added to achieve the total score for each leg.

Data for participants' characteristics included age, sex, present illness, ADLs,[26] body mass index (BMI), total serum protein level, serum albumin level, and medication use. The time spent walking, sitting, and lying down was recorded. In addition, the principal researcher measured participants' triceps skinfold, arm circumference, and arm muscle circumference and performed a Stemmer's test. This test was performed by pinching and lifting a skinfold at the base of the second toe. If the skin can be pinched and lifted, the Stemmer's sign is negative, whereas if it cannot be pinched and lifted, the sign is positive. A positive Stemmer's sign means the patient has subcutaneous tissue fibrosis.[27]

Analysis

Mann–Whitney U tests were used to compare differences in age, height, weight, and BMI between the intervention and control groups. Fisher's exact tests were used to compare differences in other characteristics between the two groups. The total number of legs of the participants were used to assess the pitting score, leg volume, and SEF. Edema severity at baseline and leg volume changes were analyzed for the intervention and control groups using Mann–Whitney U tests. Differences in pitting and SEF scores at pre- and post-intervention in each group were analyzed using the Mann–Whitney U test. Values are shown as median (interquartile range [IQR]). To determine if chronic leg edema was controlled,

participants were divided into edema-controlled and edema uncontrolled groups. Controlled edema indicated a lower or similar total pitting score at post- than at pre-intervention. Uncontrolled edema indicated that the total pitting score at post-intervention was higher than at post-intervention. Chi-square tests were used to assess the association between the intervention and edema control groups. $P < 0.05$ was considered significant. All analyses were performed using the Statistical Package for the Social Sciences version 19 (IBM-SPSS, Inc. Chicago, IL, USA).

Ethical considerations

The present study was conducted in accordance with the Helsinki declaration and was approved by the ethical review board at Kanazawa University (approval number: 599-1). This study was implemented after obtaining the participants' and their families' written informed consent. All measurements and intervention sessions were performed by two registered nurses to ensure participants' safety. Moreover, participants' vital signs were evaluated at pre- and post-vibration every day (the intervention group) to its effects on the circulatory systems.

Results

Participants and characteristics

A total of 104 participants were recruited. Among them, 21 participants included in this study were divided into 10 participants in the intervention group and 11 in the control group. Three and four participants in the intervention and control groups could not complete the study due to the limited study duration; therefore, only seven participants were analyzed for each group (Figure 3). The median age was 86 and 84 years in the intervention and control groups. Differences in participants' characteristics were not significant between the groups. Differences in the edema status at baseline in the pitting score, leg volume, and SEF were not significant between the two groups (Table 1). No adverse events due to excitation or measurement occurred in this study.

Table 1. Participants' characteristics

	Intervention (n = 7)	Control (n = 7)	*P*
Age (years), median (IQR†)	86 (85－87.5)	84 (80－89.5)	0.31
Male, n (%)	1 (14.3)	4 (57.1)	0.13
Body mass index (kg/m^2), median (IQR)	23.4 (22.2－25.1)	22.6 (22.1－25.0)	0.41
Disease, n (%) (based on ICD-10)			
Mental and behavioural disorders	4 (57.1)	3 (42.9)	0.50
Diseases of the circulatory system	4 (57.1)	6 (85.7)	0.28
Endocrine, nutritional and metabolic diseases	2 (28.6)	5 (71.4)	0.14
Diseases of the digestive system	0 (0.0)	1 (14.3)	0.50
Diseases of the genitourinary system	1 (14.3)	1 (14.3)	0.77
Diseases of the musculoskeletal system and connective tissue	4 (57.1)	1 (14.3)	0.27
Neoplasms	0 (0.0)	0 (0.0)	-
Taking diuretic medicine, n (%)	2 (28.6)	1 (14.3)	0.50
Taking medicine that couse edema as side effect, n (%)	4 (57.1)	6 (85.7)	0.28
ADL‡, n (%)	A:2 (28.6) B:5 (71.4)	A:1 (14.3) B:6 (85.7)	0.28
Standing time of a day (minutes), median (IQR)	15 (0－37)	0 (0－30)	0.09
Sitting time of a day (minutes), median (IQR)	740 (662－747)	675 (630－753)	0.80
Lying time of a day (minutes), median (IQR)	660 (660－762)	708 (638－772)	0.85
Total serum protein (g/dL), median (IQR)	7.0 (6.6－7.0)	7.0 (6.3－7.1)	1.00
Serum albumin (g/dL), median (IQR)	3.8 (3.7－3.9)	3.7 (3.6－3.9)	0.78
Positive Stemmer sign, n (%)	5 (71.4)	6 (85.7)	0.50
	Intervention (n = 14)	Control (n = 14)	
Total pitting score (points)	14.0 (10.3－16.8)	9.5 (6.0－14.5)	0.25
Leg volume (cm^3)	1079.3 (1031.5－1251.3)	1083.6 (984.7－1183.2)	0.80
Total SEF (points)	7.5 (5.3－8.0)	8.0 (4.3－9.0)	0.43

† IQR: Interquartile range

‡ ADL: Activities of daily living indicates bedridden level.

According to the “Criteria for the determination of the daily life independence level of the elderly patient with disability.”

Grade A

Almost independent for indoor daily life, but cannot go outside without care.

1. Go out with assistance, and stay away from the bed most of the daytime.
2. Do not go out so much, and get in and out of bed in daytime.

Grade B

Require some sort of care for an indoor daily life and stay in bed most of the time but can maintain a sitting position.

1. Eat and visit toilets away from bed using wheelchairs.
2. Require assistance to get on wheelchairs

Primary outcome

The total pitting score at post-intervention was significantly higher than that at pre-intervention in the control group (median 9.5 [IQR: 4.5–15.5] vs. 8.0 [3.5–11.5], $P = 0.04$) (Table 2). The median total pitting score change in the intervention group was −0.4 (IQR: −5.3–1.8), which was significantly lower than that of the control group (2.0 [IQR: 1.0–5.3], $P = 0.01$) (Table 3). A significant interaction was found (χ^2 (1) = 5.25, $P = 0.02$). The intervention group was more likely to have controlled edema (64.3%) than the control group (21.4%) (Table 4).

Secondary outcomes

The leg volume and total SEF did not significantly differ at pre- and post-intervention in both groups (Table 2). The leg volume and SEF changes did not significantly differ between the two groups (Table 3).

Table 2. Edema status changes at pre- and post-intervention

	Intervention (n=14)			Control (n=14)		
	Pre	Post	*P*	Pre	Post	*P*
Total pitting score (points)	14.5 (11.8 – 18.0)	11.5 (7.0 – 18.6)	0.06	8.0 (3.5 – 11.5)	9.5 (4.5 – 15.5)	0.04*
Leg volume (cm^3)	1079.3 (1031.5 – 1251.3)	1055.5 (994.6 – 1260.4)	0.45	1083.7 (984.7 – 1183.1)	1085.7 (942.5 – 1216.2)	0.98
Total SEF (points)	7.7 (4.3 – 8.0)	6.5 (4.5 – 8.0)	0.36	8.0 (4.0 – 9.3)	6.0 (5.0 – 9.3)	0.59

Value indicate that median (IQR).

Table 3. Comparison of edema status changes between the intervention and control groups

	Intervention (n = 14)		Control (n = 14)		*P*
Total pitting score changes (points)	-0.4	(-5.3 – 1.8)	2.0	(1.0 – 5.3)	0.01*
Leg volume changes (cm^3)	0.01	(-72.74 – 31.50)	0.85	(-18.37 – 30.93)	0.57
Total SEF changes (points)	0.0	(-1.0 – 0.3)	0.0	(-1.3 – 1.0)	0.84

Values are presented as median (IQR).

Table 4. Association between the intervention and controlled edema

	Intervention (n=14)	Control (n=14)	*P*
Controlled†, legs (%)	9 (64.3)	3 (21.4)	0.02*
Uncontrolled‡, legs (%)	5 (35.7)	11 (78.6)	

The test result denoted the Chi-square value as 5.25 at df=1.

† Controlled: The total pitting score at post-intervention was lower or similar with that at pre-intervention.
‡ Uncontrolled: The total pitting score at post-intervention was higher than that at pre-intervention.

Discussion

Results of the present study indicate that vibration can effectively prevent the progression of chronic leg edema. This was the first study to evaluate the effects of vibration for chronic leg edema among chair-bound elderly individuals.

In this study, the total pitting score at post-intervention was significantly higher than that at pre-intervention in the control group. Moreover, the median total pitting score change in the intervention group was significantly lower than that in the control group, indicating that the chronic leg edema in elderly individuals worsens without vibration in this study. Furthermore, these results were consistent with those reported by a previous study, showing that edema severity significantly increased over time in elderly individuals with chronic leg edema.[28]

We considered that chronic leg edema can be prevented from worsening with vibration through the following mechanisms. The first mechanism is due to venous function. Edema reduction with vibration includes vasodilation due to axon reflex[29] or increased secretion of endothelium-derived nitric oxide.[30] These factors increased the blood flow and reduced the venous pressure, which promote interstitial fluid reabsorption. Another mechanism is caused by the function of superficial lymphatic vessels. Anchoring filaments are expanded through vibration stimulation by promoting interstitial fluid reabsorption to the superficial lymphatic vessels.[17]

In this study, differences in the secondary outcome were not significant. We considered some reasons as follows. Regarding the leg volume results, edema severity changes in the foot cannot be measured because leg volumes were calculated except for the dorsal pedis in this study. Elderly individuals with decreased walking ability often have severe edema in their ankles or feet.[31] Thus, volume changes in the feet possibly occurred. With regard to SEF, edema status changes were not reflected in the SEF score. SEF changes were assessed using the modified SEF grade in our study. This assessment tool has only five grades and could not reflect detailed interstitial fluid changes. Moreover, the proportion of positive Stemmer signs was high in this study. Positive Stemmer's sign indicates the patient has subcutaneous tissue fibrosis.[27] Therefore, a tissue change that did not appear in the morphological echo image change may occur.

This is the first study that used vibration for the treatment of chronic leg edema in chair-bound elderly individuals. In this study, no adverse events such as abnormal cardiovascular function or skin damage were caused by the intervention. The vibration intensity used in this study has been proven safe for humans including elderly individuals in previous studies.[16, 22] Therefore, vibration can be adopted to prevent deterioration of chronic leg edema safely in chair-bound elderly individuals.

This study has four limitations. First, participants' body position was not uniform when providing vibration. Previous studies showed that planter vibration increased the leg fluid flow.[17] In this study, some participants underwent the vibration therapy in a sitting position because it was performed under a condition that did not interfere the participants' daily life. However, extreme knee flexion has been shown to decrease the ankle brachial systolic pressure index.[32] Therefore, we considered that a sitting position for vibration might have affected the results. Intervention conditions should also be considered in future studies, and more effective care methods examined. Second, this study included few participants because only chair-bound elderly individuals were included. In Japanese nursing homes, the independence revel of residents was decreasing in recent years, and therefore, several residents were excluded from this study. Third, the group assignment was not blinded for the outcome assessment. Finally, only one vibration condition was performed; the frequency and horizontal vibration acceleration were always set at 47 Hz and 1.78m/s^2, respectively. Other vibration conditions could therefore not be assessed in this study. Further studies are required for more thorough investigations using trials with larger sample sizes and other intervention conditions.

Conclusions

Pitting scores, leg volumes, and SEFs were measured at pre- and post-vibration therapy in chair-bound elderly individuals. The total pitting score at post-intervention was significantly higher than that at pre-intervention in the control group. The median total pitting score change in the intervention group was significantly lower than that in the control group. Moreover, the intervention group was more likely to have controlled edema than the control group. These results indicate that vibration can prevent the deterioration of chronic leg edema in chair-bound elderly individuals.

Abbreviations

QOL, quality of life; SEF, subcutaneous echo-free space grade; US, ultrasound; BMI, body mass index; IQR, interquartile range

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Helsinki declaration and approved by the ethical review board at Kanazawa University (approval number: 599-1). Participants and their families were informed about the study aim, data confidentiality, and voluntary participation, and thereafter, written informed consent was obtained from all of them.

Consent for publication

Not applicable.

Availability of data and materials

Datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declared to have no competing interests.

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Authors' contributions

ST, MD, MO, TN, and JS contributed to the study conception and design; ST, AS, and TU collected data; ST performed the statistical analysis; ST drafted the manuscript; and MD, MO, TN, and JS critically reviewed the manuscript and supervised the entire study process. All authors read and approved the final manuscript.

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Figures

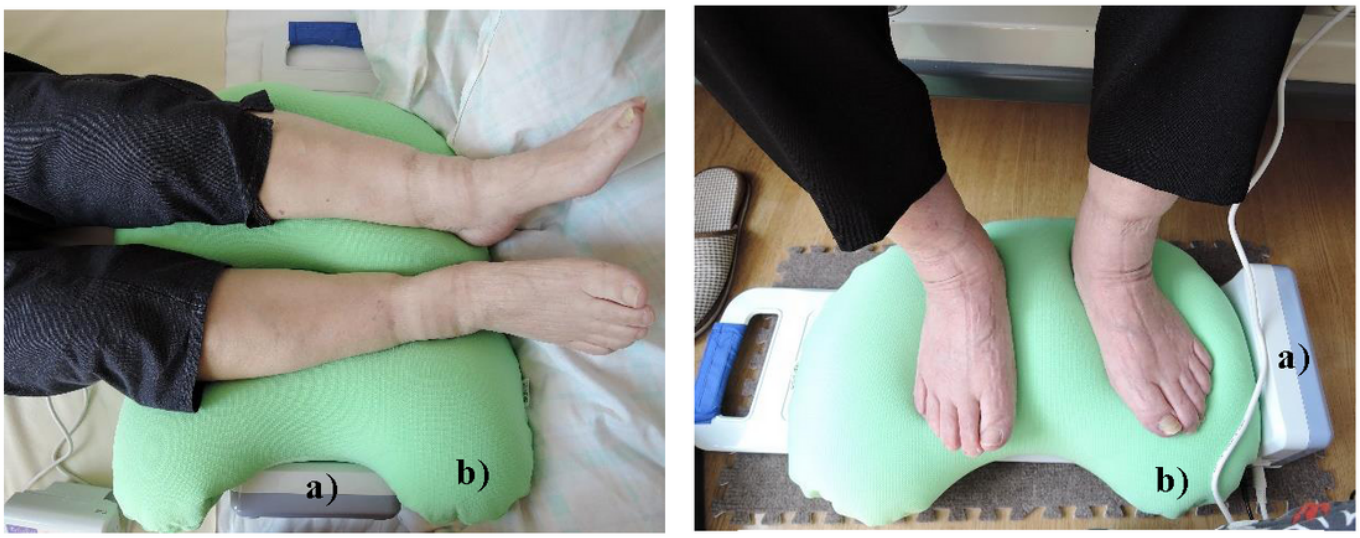

Figure 1

Intervention method Legend a) Vibration device, b) Cushion Vibrations were provided in supine position (A) or sitting position (B). The size of the vibration device (Rela feel, Global-Micronics Co., Ltd. Kashiwa, Japan) was 616×182×114 mm (length×width×height). The vibrator was placed under the legs with cushions (270 mm long, 430 mm wide, 120 mm thick) between the vibrator.

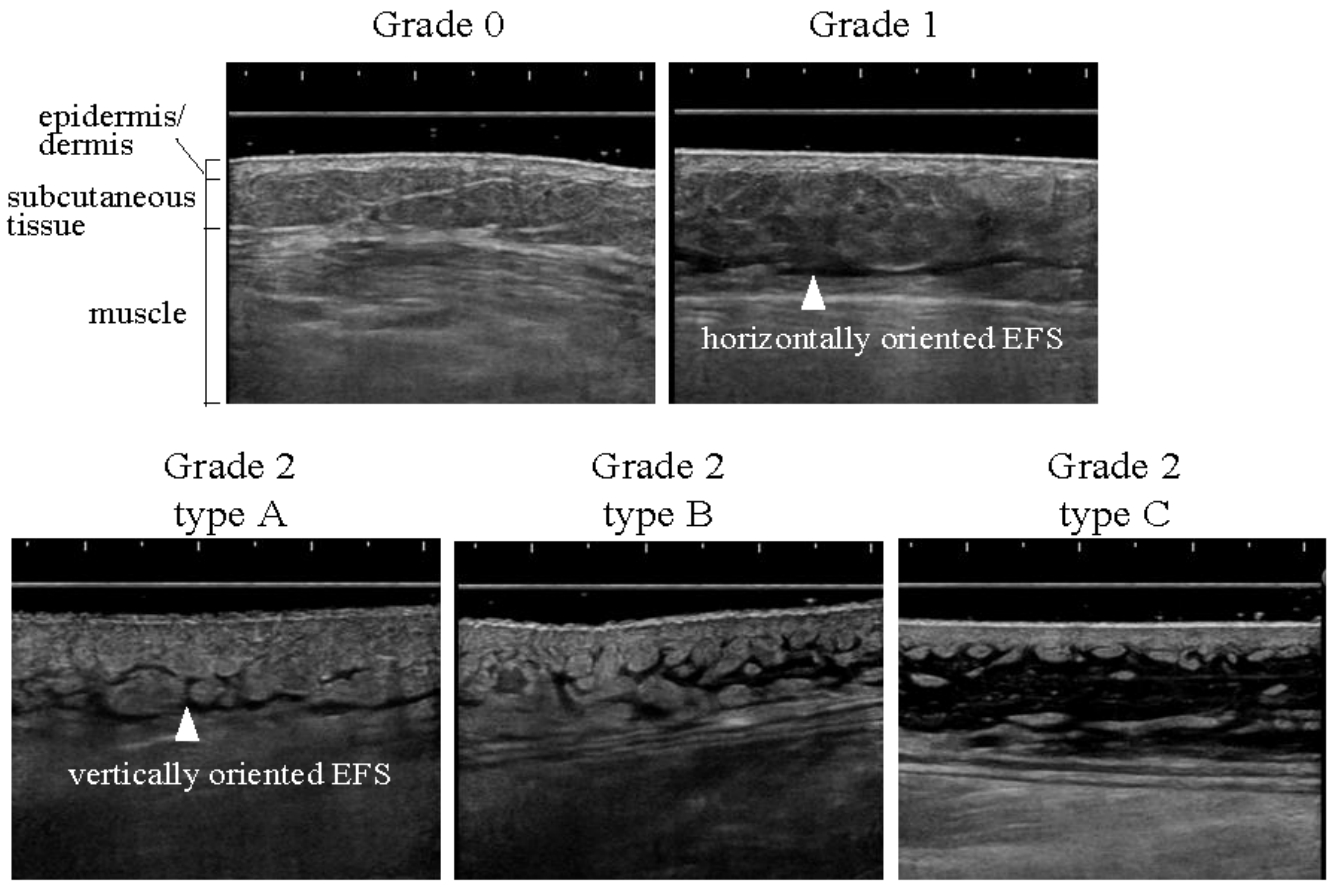

Figure 2

Modified Subcutaneous Echo Free Space Grade Legend Grade 0: No echo free space (EFS). Grade 1: Horizontally oriented (<45 degrees to the skin) only. Grade 2 / type A: Presence of vertically oriented (≥45 degrees to the skin), EFS bridging the horizontally oriented EFSs, EFS occupies less than 20% of subcutaneous tissue area. Grade 2 / type B: Presence of vertically oriented (≥45 degrees to the skin), EFS bridging the horizontally oriented EFSs, EFS occupies 20% or more, but less than 80%. Grade 2 / type C: Presence of vertically oriented (≥45 degrees to the skin), EFS bridging the horizontally oriented EFSs, EFS occupies 80% or more.

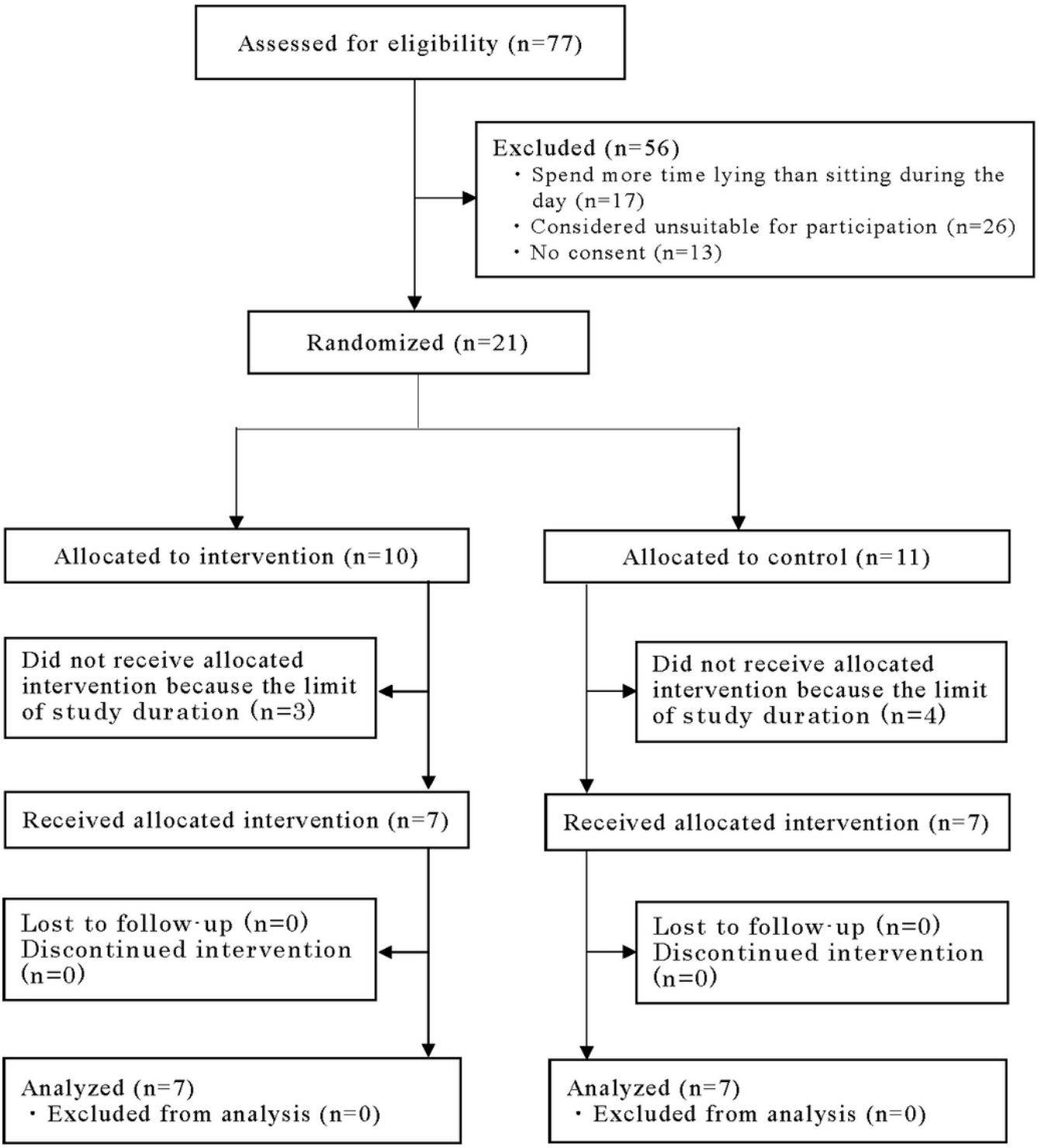

Figure 3

Flow of study participants

Supplementary Files

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- CONSORT2010Checklist.doc