

STUDY PROTOCOL

THE EFFECT OF VIRTUAL REALITY EXERGAME ON PHYSICAL ACTIVITY AND FITNESS IN THE ELDERLY

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CHAPTER I

BACKGROUND

As individuals age, there is a decline in biological, physiological, and functional capacities (Russo et al., 2012; Kushkestani, Parvani, and Moghadassi, 2020). Functional declines such as muscle strength, endurance, flexibility, balance, mobility, and speed (Verbrugge, Latham, and Clarke, 2017) lead to an inability to perform daily activities such as walking, sitting, and standing (Conrad, Cermak, and Drake, 1983). This, in turn, impacts the quality of life of older adults. A recent approach to evaluating quality of life, in addition to **Life Expectancy**, is **Healthy Adjusted Life Expectancy (HALE)**. The average HALE in Indonesia is 62.25 years, meaning 8.85 years are lost due to chronic diseases and disabilities (Ministry of Health of the Republic of Indonesia, 2020).

One strategy for managing chronic diseases and disabilities sustainably is through prevention via physical activity, such as exercise/sports (Braith and Stewart, 2006; Yeom, Jung, and Choi, 2011). The World Health Organization's (WHO) exercise recommendations include aerobic exercise, strength training, flexibility, and balance exercises to reduce the risk of falls (Chodzko-Zajko et al., 2009). Aerobic exercise stimulates the heart, lungs, all muscle groups, and results in beneficial changes to the body and mind (Brown et al., 2009).

Scientific evidence shows that the success of physical exercise depends on **adherence to exercise**, and among older adults, adherence and motivation tend to be low. This is due to external factors such as mobility difficulties, distance, or lack of adaptation to the environment of exercise centers (Brown et al., 2009). Therefore, it is crucial to consider interventions that improve exercise success among older adults, particularly due to issues of adherence and motivation. One such intervention is through **exergames** (Fragala et al., 2019).

Exergames are physical exercises combined with active play or sports (i.e., active video games or sports-based games), serving not only as entertainment but

also as a strategy to improve the fitness of older adults (Fragala et al., 2019). Exergames also incorporate elements of immersive virtual reality (VR). Virtual reality (VR) is an active video game that controls body movements within a safe environment, involving physical activity and interaction. One VR exergame, the **Nintendo Switch RingFit Adventure (RFA)**, is a novel exergame that integrates resistance training, aerobic exercise, and balance. VR exergames can address the limitations of repetitive and monotonous physical exercise by offering an engaging and multisensory game environment where interaction occurs through full-body movements (Tuan et al., 2022).

According to a systematic review, VR exergame interventions can improve physical function, reduce symptoms of depression and anxiety, and enhance health-related quality of life (Rosenberg et al., 2010; Villafaina et al., 2020). However, research using the **Nintendo Switch RingFit Adventure (RFA)** rarely focuses on fitness levels and physical activity in older adults. Therefore, the researcher is interested in investigating the effectiveness of **virtual reality exergames** on fitness levels and physical activity in older adults.

CHAPTER II

RESEARCH METHODS

2.1 Research design

This study is an experimental study with a randomized controlled trial – double blind research design. The researchers and data processor (statisticians) conducting this experimental study are blinded, meaning it's unaware of the distribution of samples in the intervention and control groups.

2.2 Place and time of research

The research will be conducted from February 2024 to June 2024 by taking a population of elderly people in Makassar City.

2.3 Population and sample

a. Population

Population is the whole object of research. The target population in this study were all elderly people in Makassar City. The affordable population is the elderly at Olive Elderly Community in Makassar City who meet the inclusion criteria.

b. Sample

The sample is a portion taken from the entire subject under study and is considered representative of the entire population. The sample of this study was 40 subjects who were randomly selected and divided into 2 groups.

2.4 Sample Size

The sample size formula for the two mean difference hypothesis test for numerical variables is as follows :

$$n = \frac{(Z_a + Z_b)^2 \cdot 2 \cdot (s)^2}{d^2}$$

Z_{α} : Z value for type 1 error

Z_{β} : Z value for type 2 error

s^2 : variance of the difference of 2 mean pairs

d^2 : mean estimate before intervention

Based on previous research, the value of $s^2 = 3,6$ and value $d = 3,7$ (Wu *et al.*, 2023). Value $Z_{\alpha} = 1,96$ with a confidence interval of 95% and value $Z_{\beta} = 0,84$ with 80% power so that,

$$n = \frac{2 \times 3,6 [1,96 + 0,84]^2}{(3,7)^2}$$
$$n = 7$$

To anticipate the occurrence of dropouts in subjects, corrections were made by :

$$N = n/(1-f)$$

Description =

N = correction sample size

n = initial sample size

f = estimated dropout proportion of 20%

so

$$N = 7/(1-20\%)$$

$$N = 7/(1-0,2)$$

$$N = 7/0,8$$

$$N = 8,75 \approx 9$$

This research also has categorical variables, so the sample size formula for randomized controlled trial hypothesis testing of dichotomous variables with clinical superiority design is as follows (Zhong, 2009) :

$$n = 2 \times \left(\frac{Z_{1-\alpha} + Z_{1-\beta}}{d - \delta_0} \right)^2 \times p \times (1 - p)$$

n = size per group

p = group response rate (0,5)

$Z_{1-\alpha}$ = degree of confidence 95% (1,96)

$Z_{1-\beta}$ = power 80% (1.84)

d = difference in effect between two groups

δ_0 = clinically acceptable values

Based on previous research, the value of d = 2,5 (Yang *et al.*, 2020) and value $\delta_0 = 2$ (Wright *et al.*, 2011), so

$$n = 2 \times \left(\frac{1,96 + 0,84}{2,5 - 2} \right)^2 \times 0,5 \times (0,5)$$

$$n : 15,68 \approx 16$$

To anticipate the occurrence of dropouts in subjects, corrections were made by :

$$N = n/(1-f)$$

Description =

N = correction sample size

n = initial sample size

f = estimated dropout proportion of 20%

so

$$N = 16/(1-20\%)$$

$$N = 16/(1-0,2)$$

$$N = 16/0,8$$

$$N = 20$$

Based on the sample formula used, each group had a minimum of 20 subjects with a total of 40 subjects divided into 2 groups to reduce bias. The first group is the Ring Fit Adventure virtual reality exergame training group as the intervention group and the second group is the elderly aerobic exercise group from KEMENKES as the control group. The sampling technique used was cluster randomized controlled trial.

2.5 Inclusion, Exclusion, and Drop Out Criteria

Inclusion criteria :

1. Participation in the research
2. Aged > 60 years old
3. Able to watch television with or without glasses from a distance of 2 meters (visus 20/20 - 20/80)
4. No cognitive impairment (MOCA-Ina score: 26-30)

Exclusion criteria :

1. Congestive heart failure disease
2. Uncontrolled hypertension
3. Fracture or history of surgery in the last 6 months
4. Currently on the waiting list for orthopedic surgery
5. Myocardial infarction or stroke in the last 6 months
6. Wheelchair dependent
7. Severe hearing and vision impairment
8. Other neuromusculoskeletal disorders that interfere with the ability to perform exercises (pain with VAS >4)

Drop out criteria

Patients were excluded from the study if :

1. Participant died
2. Participant attended the exercise <3 times for 2 consecutive weeks
3. Participant refused to continue training sessions
4. Participant felt any of the symptoms of intervention side effects/cybersickness 2x consecutive training sessions
5. Participant experienced exacerbated hemodynamic and neurological impairment during training

2.6 Data Collection

This study used 40 subjects taken from the elderly population. The subjects were selected based on the inclusion and exclusion criteria. After that, the research subjects

will be grouped into virtual reality exergame group as the intervention group and aerobic exercise group as the control group using randomization method.

1. Pre-Intervention

Firstly, participants who fit the inclusion criteria were educated and consented to the study. Next, participants were interviewed about their identity, place and date of birth, age, address, marital status and occupation, history of physical activity and exercise in the last 3 months, history of illness and routine medication use, history of surgery, ability to watch TV within 2 meters with or without glasses and dependence on a wheelchair. After that, a physical examination will be conducted which includes vital signs and an examination of the participant's nutritional status which includes weight, height, and body mass index.

In addition, participants will be subjected to several examinations to assess the variables in this study in the form of :

- International Physical Activity Questioner (IPAQ) – Short Form Indonesian Version

Participants will be given an International Physical Activity Questionnaire (IPAQ) - Short Form Indonesian version questionnaire assessed to measure participants' daily physical activity carried out independently by participants before and after the intervention for 6 weeks.

- 30 second-sit-to-stand test

The 30-second sit-to-stand test is conducted to assess lower extremity muscle endurance. This test uses a chair that has a backrest, no armrests, a hard chair seat, and adjustable chair leg length. During the examination procedure, the participant will be instructed to sit in the center of the chair and the height of the chair will be adjusted to the height of the participant's fibula bone (or 17 inches). Then, participants will be instructed to cross their arms over their chest, ensuring that both feet touch the floor in a neutral position with the hips and knees in a 90-degree flexion position. The participant will be seated in an upright position and instructed to start the sit-to-stand cycle upon the "start" signal. Cycles will be counted from sitting to upright standing and back to sitting. Outcome measures

will be based on the number of sit-to-stand cycles within 30 seconds that will be used.

- Hand muscle strength

This examination uses a handgrip dynamometer brand CAMRY ISO 9001 model EH101 with a static method. Participants were asked to firmly grasp the tool according to the participant's ability in the dominant and non-dominant hands. During the measurement, participants were asked to stand, bend their elbows 90 degrees, and grip the handgrip dynamometer using the dominant/non-dominant hand three times as hard as possible while holding their breath for 5 seconds, and rest 15 seconds for a break in each measurement to prevent fatigue. The highest measurement (in kilograms) of the dominant/non-dominant hand will be recorded.

- Flexibility

This examination uses the chair-sit-and-reach test. Participants were asked to sit on the edge of a chair with their feet on the floor at a distance of 6-12 inches to the body line and stretch the other leg forward with the knee in extension, the heel resting on the floor with a neutral ankle position of 90 degrees. Then participants were instructed to inhale and then exhale while reaching for the toes by bending the hips, with the knee remaining in extension, and the grip was held for 2 seconds. Scores were recorded using a ruler parallel to the Tibia bone, the center of the toe representing a score of "zero". A shorter reach of the toes was recorded as a minus score, and a longer reach of the toes was recorded as a plus score.

- Body composition

This examination will use a bioimpedance analysis (BIA) tool to measure body fat mass and fat-free mass, which includes muscle and bone. First, turn on the BIA device, then enter your age, weight, height, and gender. After that, stand on the device and press the start measurement button and wait a few moments to see the results.

Furthermore, participants will be subjected to additional examinations in this research in the form of :

- MOCA-Ina

Participants will be evaluated for cognitive function using the Montreal Cognitive Assessment (MOCA) - Indonesian version before the intervention.

- Borg Scale

Participants will be screened to measure the level of physical activity intensity using the Borg scale before the intervention.

Secondly, the participant underwent a pre-exercise protocol which consisted of screening for risk factors and contraindications, a 6-minute walk test, introduction to the explanation of equipment use, and recommended clothing to be used during exercise. This pre-exercise protocol will be done only once at the beginning before the intervention. Education in the form of an introduction to the virtual reality exergame tool - Nintendo Switch Ring Fit Adventure in the intervention group and an elderly aerobic exercise video in the control group.

2. Intervention

Participants will first warm up for 5-10 minutes. After that, the intervention group participated in the virtual reality exergame training using the Nintendo Switch Ring Fit Adventure in a quiet, obstacle-free room with different durations for each session. If any participant felt symptoms of cybersickness (fatigue, headache, nausea, difficulty focusing, sweating, or dizziness), the training was stopped and the participant was given initial treatment according to the symptoms experienced. If the symptoms disappear after the initial treatment is given, participants are allowed to continue the exercise. However, if the symptoms persist for 30 minutes after the initial treatment is given, the participants will be taken to the nearest health service by the researcher. Exercise in the intervention group is given for 6 weeks and will be done 3x exercise/week.

Meanwhile, the control group will perform conventional exercises using aerobic exercise procedures that will be supervised by a physiotherapist. The physiotherapist

will supervise the exercises performed by the participants in the control group. Exercise in the control group is given for 6 weeks and will be done 3x exercise/week.

Hemodynamic monitoring was carried out before and after the intervention, in addition, the intensity of the exercise was monitored based on Heart Rate Reserved 40%-60% and RPE scale 12-13.

3. Post Intervention

After the training session ends at week 6, data will be collected again the next day in the form of physical examination data, physical activity assessment physical activity assessment (IPAQ), hand muscle strength assessment (handgrip dynamometer), limb endurance assessment (30 second sit to stand test), flexibility assessment (chair sit and reach test), and body composition assessment (BIA).

Both groups will be given progressive overload as shown in table 4.1 according to research conducted by Wu et al in 2023, which is modified by the researcher in the form of monitoring the intensity level before and after training each session based on heart rate reserved using a switch tool on the Ring Fit or RPE scale 12-13.

Table 2. 1 Exercise duration in research (Wu et al., 2023).

Description	Duration (minute)
a. Warming up Dynamic stretching (neck, arms, hands, hips, legs, and ankles) according to KEMENKES aerobic exercise video	10
b. Exercise <u>Intervention</u> VR Exergame (Frequency = 3 day/week; Intensity [<i>Heart Rate Reserved</i> = 40%-60% and RPE scale 12-13]; aerobic type) • Phase 1 (Week 1) : Exercise with the <i>beginnia</i> game program (2 sets of 2 minutes each), then <i>moenster den</i> (2 sets of 3 minutes each set).	10

Description	Duration (minute)
<ul style="list-style-type: none"> Phase 2 (Week 2) : Exercise with the <i>beginnia</i> game program (2 sets of 2 minutes each), then <i>trotter's groove</i> (2 sets of 3 minutes each set). 	10
<ul style="list-style-type: none"> Phase 3 (Week 3) : Exercise with the <i>beginnia</i> game program (1 set with a game duration of 2 minutes each set), then <i>moenster den</i> (2 sets with a game duration of 3 minutes each set), then <i>sportan highway</i> (1 set with a game duration of 7 minutes each set). 	15
<ul style="list-style-type: none"> Phase 4 (Week 4) : Exercise with the <i>beginnia</i> game program (1 set with a game duration of 2 minutes each set), then <i>moenster den</i> (1 set with a game duration of 3 minutes each set), then <i>starting block bridge</i> (2 sets with a game duration of 4 minutes each set), then <i>sportan highway</i> (1 set with a game duration of 7 minutes each set). 	20
<ul style="list-style-type: none"> Phase 5 (Week 5) : Exercise with the <i>beginnia</i> game program (1 set with a game duration of 2 minutes per set), then <i>dragon stadium 2</i> (1 set with a game duration of 2 minutes per set), then <i>moenster den</i> (2 sets with a game duration of 3 minutes per set), then <i>starting block bridge</i> (2 sets with a game duration of 4 minutes per set), then <i>sportan highway</i> (1 set with a game duration of 7 minutes per set). 	25
<ul style="list-style-type: none"> Phase 6 (Week 6) : Exercise with the <i>dragon stadium 2</i> game program (1 set with a game duration of 2 minutes each set), then <i>moenster den</i> (2 sets with a game duration of 3 minutes each set), then <i>starting block bridge</i> (2 sets with a game duration of 4 minutes each set), then <i>sportan highway</i> (2 sets with a game duration of 7 minutes each set). 	30
<p><u>Control</u></p> <p>Aerobic exercise (Frequency = 3 day/ week; Intensity [<i>Heart Rate Reserved</i> = 40%-60% and RPE scale 12-13]; aerobic type)</p>	

Description	Duration (minute)
<ul style="list-style-type: none"> • Phase 1 (Week 1) : Aerobic exercise with a duration of 10 minutes 	10
<ul style="list-style-type: none"> • Phase 2 (Week 2) : Aerobic exercise with a duration of 10 minutes 	10
<ul style="list-style-type: none"> • Phase 3 (Week 3): Aerobic exercise for 10 minutes, then strength exercise for 5 minutes. 	15
<ul style="list-style-type: none"> • Phase 4 (Week 4): Aerobic exercise for 10 minutes, then strength exercise for 10 minutes. 	20
<ul style="list-style-type: none"> • Phase 5 (Week 5): Aerobic exercise for 15 minutes, then strength exercise for 10 minutes. 	25
<ul style="list-style-type: none"> • Phase 6 (Week 6): Aerobic exercise for 15 minutes, then strength exercise for 15 minutes. 	30
<p>c. Cooling down</p> <p>Static Stretching (neck, arms, hands, hips, legs, and ankles) according to KEMENKES aerobic exercise video</p>	10

2.7 Data Collection

The data collected is primary data obtained in accordance with the inclusion criteria. Samples who are willing to become research subjects will be interviewed, physical examinations, examinations to assess variables including physical activity using the Indonesian version of the International Physical Activity Questionnaire (IPAQ) Short Form and physical fitness in the form of body composition, hand muscle strength, limb muscle endurance, and flexibility.

The interview questionnaire in this study will contain a list of participant identities including name, age, marital status, address, education history, employment history, activity and exercise history in the last 3 months, self-reported vision ability.

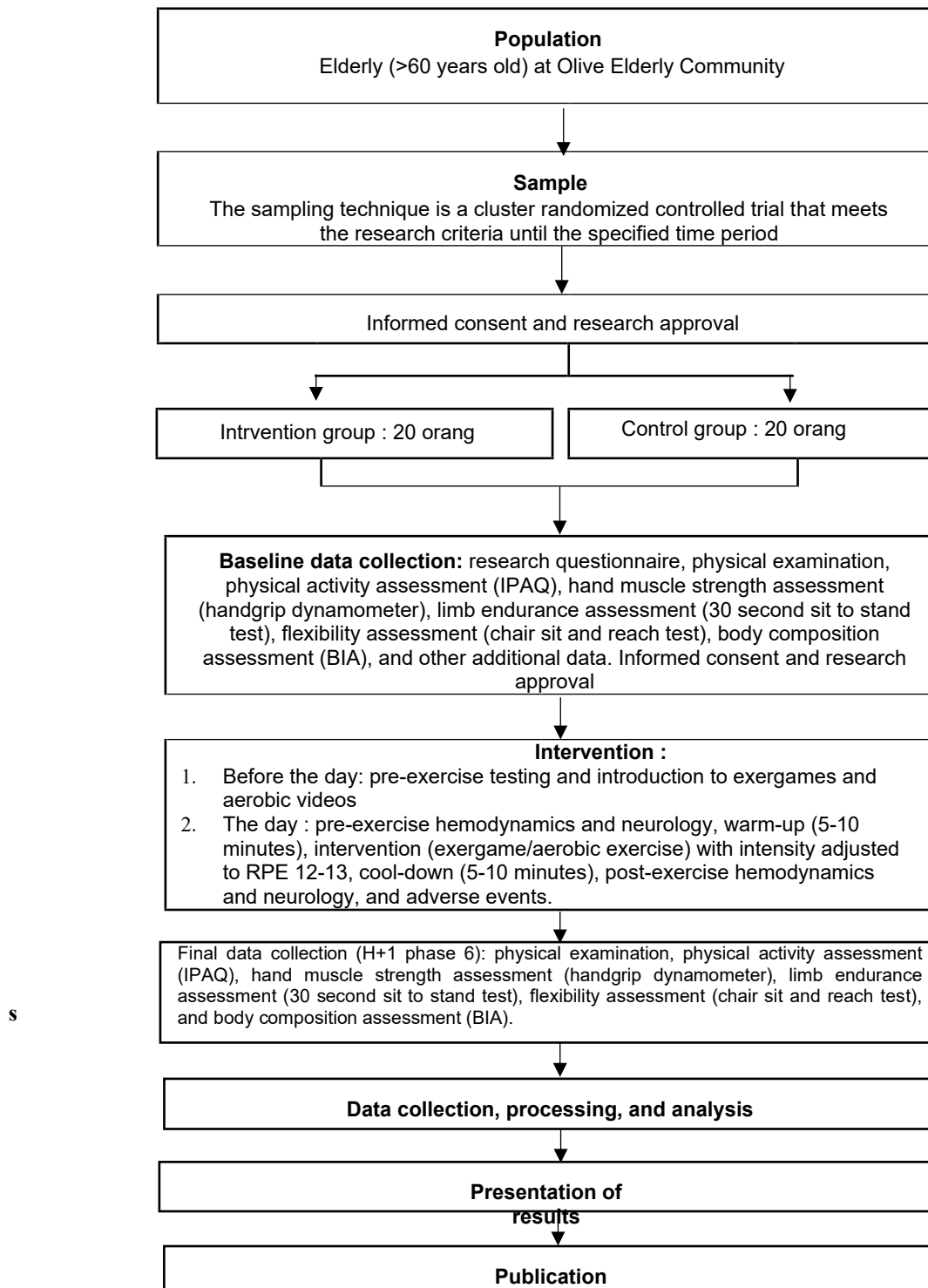
2.8 Research Instrument

In supporting the research process, support is needed in the form of :

1. Research ethics permission letter
2. Sheet explaining the respondent's actions and consent
3. Screening sheet and MOCA-Ina
4. Test form sheet (International Physical Activity Questionnaire (IPAQ) questionnaire, body composition, handgrip dynamometer, 30 second sit to stand, chair sit and reach test)
5. Intervention adverse effect sheet
6. Nintendo Switch + Ring Fit game equipment
7. Projector + LCD or television
8. KEMENKES aerobic exercise video at the link:
https://www.youtube.com/watch?v=YiA_n0q18LA&t=1888s
9. Bioelectrical impedance analysis (BIA) brand Tanita BC 730
10. Electronic hand dynamometer brand CAMRY ISO 9001 model EH101
11. Stopwatch
12. Sphygmomanometer brand OMRON and stethoscope brand litman
13. Meter measuring tape
14. Pen
15. Chair with backrest without armrest

16. Computer and data analysis software SPSS version 23
17. Digital camera (research documentation tool)
18. Oxygen transfer, nasal cannula, and oxygen saturation/oximeter brand
General Care
19. Wheelchair
20. Mattress
21. Gurney

2.9 Research flow



Picture 2. 1 Research Flow

2.10 Statistical Analysis Plan

- The data obtained will be subjected to descriptive analysis to explain the characteristics of the participants.
- This study will be analyzed by chi square or mc nemar (categorical dependent variables) and t test (numerical dependent variables).
- Data on the effects of VR exergames compared to aerobic exercise training will be assessed using independent t test (normally distributed data) and nonparametric man whitney test (non-normally distributed data).
- On the numerical dependent variable, normality and homogeneity tests (Kolmogrov-Smirnov) will be conducted. Data is said to be normally distributed if the p value is >0.05 .
- Interpretation of the results will be comprehensively discussed between researchers and a team of experts in each field to draw appropriate conclusions.
- The relationship between each parameter will be assessed using Pearson correlation test (normally distributed data with numerical dependent variable) or Spearman test (categorical-ordinal variable) or contingency coefficient (categorical-nominal variable) to determine how much correlation between the variables.
- The assessment of effectiveness between virtual reality exergame (Intervention) and aerobic exercise (control) will be analyzed by logistic regression.
- Data will be processed and analyzed using SPSS version 23.

2.11 Ethics

Before the research :

- a. Researchers took care of ethical licensing at the ethics commission of the Faculty of Medicine, Hasanuddin University.
- b. Apply for permission to the Chairperson of the Elderly Community.

During the research :

- a. All research procedures were only carried out if participants were willing to become research subjects.
- b. Virtual reality exergame was taught and supervised by a doctor specializing in physical medicine and rehabilitation.
- c. Aerobic exercise was taught and supervised by a general practitioner.
- d. If the research subjects felt tired or had other medical complaints during the exercise, the exercise would be stopped and focused on managing the symptoms of the research subjects (appendix 7).

After the research :

- a. Keeping the personal identity of the research subjects from the public.
- b. All examination results conducted in the study will be delivered to each research subject.

CHAPTER III

INFORMED CONSENT



KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN UNIVERSITAS HASANUDDIN
RSPTN UNIVERSITAS HASANUDDIN
RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR
Sekretariat : Lantai 2 Gedung Laboratorium Terpadu
JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.



Contact Person: dr. Agussalim Bukhari., MMed, PhD, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

SUPPLEMENTARY 1

* informed consent in Indonesian language and approved by human subjects protection review board of hasanuddin university

FORMULIR PERSETUJUAN SETELAH PENJELASAN (PSP) (INFORMED CONSENT)

Assalamu'alaikum warahmatullahi wabarakatuh

Salam sejahtera Bapak/Ibu. Saya **dr. Andi Amirah Shaleha Junaedi** yang akan melakukan penelitian tentang **EFEKTIVITAS *VIRTUAL REALITY EXERGAME* TERHADAP AKTIVITAS FISIK DAN KEBUGARAN FISIK PADA LANJUT USIA**, kami bermaksud mengikutsertakan anda sebagai subyek pada penelitian ini.

Penelitian ini bertujuan untuk mengetahui perbandingan efektivitas *virtual reality exergame* menggunakan permainan *Nintendo Switch Ring Fit Adventure* dan senam aerobik KEMENKES terhadap aktivitas fisik dan kebugaran fisik pada lanjut usia, khususnya di Makassar. Penelitian ini diharapkan dapat memberikan pengetahuan tentang efektivitas *virtual reality exergame* dan latihan senam aerobik KEMENKES untuk peningkatan aktivitas fisik dan kebugaran fisik sehingga meningkatkan kualitas hidup pada populasi lansia.

Adapun kriteria partisipan yang akan diikutsertakan dalam penelitian ini adalah pria atau wanita berusia ≥ 60 tahun, mampu menonton televisi dengan atau tanpa kacamata dari jarak 2 meter, mampu memahami perintah dengan baik, dan tidak memiliki penyakit berat atau rasa nyeri yang dapat mengganggu kemampuan dalam melakukan latihan. Adapun kelompok penelitian akan dibagi menjadi dua kelompok yaitu kelompok perlakuan berupa latihan aerobik berbasis *virtual reality exergame* dan kelompok kontrol berupa latihan senam aerobik KEMENKES. Partisipan akan diacak ke dalam kelompok penelitian, sehingga partisipan akan masuk kelompok perlakuan atau kontrol.

Penelitian ini tidak memaksa keikutsertaan Bapak/Ibu, bersifat sukarela, dan Bapak/Ibu dapat mengundurkan diri kapan saja tanpa mengurangi hak mendapatkan pelayanan kesehatan. Adapun apabila partisipan menyetujui untuk ikut pada penelitian, maka Bapak/Ibu diharapkan mengikuti prosedur penelitian ini sampai selesai.

Adapun prosedur yang akan dilaksanakan pada penelitian ini yaitu **Pertama** berupa **wawancara** (identitas, tempat dan tanggal lahir, umur, alamat, status pernikahan dan pekerjaan, riwayat aktivitas fisik dan berolahraga dalam 3 bulan terakhir, riwayat penyakit dan penggunaan obat rutin, riwayat tindakan operasi, kemampuan menonton tv dalam jarak 2 meter dengan atau tanpa kacamata serta ketergantungan terhadap kursi roda); **pemeriksaan fisik** (meliputi tanda-tanda vital berupa tekanan darah, nadi, laju pernafasan, suhu, dan saturasi oksigen dan pemeriksaan status nutrisi partisipan yang meliputi berat badan, tinggi badan, dan indeks massa tubuh. Pemeriksaan ini akan dilakukan pada awal sebelum dan setelah latihan baik kelompok perlakuan maupun kontrol selama 6 minggu); **pemeriksaan tambahan dan pengisian kuesioner** (**aktivitas fisik** keseharian partisipan menggunakan kuesioner *International Physical Activity Questioner (IPAQ) – Short Form* Versi Indonesia; **ketahanan otot tungkai bawah** melalui *30 second-sit-to-stand test*. Pengukuran dilakukan berdasarkan jumlah siklus duduk berdiri dalam waktu 30 detik; **kekuatan otot tangan** menggunakan *spring-type dynamometer* dengan menggenggam secara kuat alat tersebut sesuai kemampuan partisipan pada tangan

dominan maupun non-dominan sebanyak tiga kali; **fleksibilitas** atau luas gerak sendi melalui pemeriksaan *chair-sit-and-reach test*. Partisipan diminta untuk menggapai jari kaki menggunakan tangan dengan posisi duduk di tepi kursi dan kaki lurus kedepan; dan **komposisi tubuh** menggunakan alat *bioimpedance analysis* (BIA) berupa massa lemak tubuh (*body fat*) dan massa bebas lemak (*fat-free mass*) yang mencakup otot dan tulang. Pemeriksaan ini akan melengkapi lembar khusus untuk pemeriksaan komposisi tubuh). Pemeriksaan tambahan ini dilakukan sebelum dan setelah latihan baik kelompok perlakuan maupun kontrol selama 6 minggu.

Selanjutnya, partisipan akan dilakukan pemeriksaan tambahan lainnya pada penelitian ini berupa : **MOCA-Ina** (pemeriksaan fungsi kognitif menggunakan *Montreal Cognitive Assessment* (MOCA) - versi Indonesia diawal sebelum dilakukan latihan baik kelompok perlakuan maupun kontrol; **Borg Scale** (pemeriksaan untuk mengukur tingkat intensitas aktivitas fisik menggunakan skala Borg sebelum dan setelah setiap dilakukan latihan baik kelompok perlakuan maupun kontrol); dan **USG diafragma dan otot quadriceps** mengukur ketebalan otot diafragma dan otot quadriceps menggunakan alat USG sebelum dan setelah dilakukan intervensi.

Kedua, berupa protokol *pre-exercise*/pre-latihan. Partisipan melakukan protokol *pre-exercise* yang terdiri dari skrining faktor risiko dan kontraindikasi dan uji latih jalan 6 menit pada hari pertama. Selanjutnya pada hari kedua pengenalan mengenai penjelasan penggunaan alat dan pakaian yang disarankan digunakan saat latihan. Protokol *pre-exercise* ini akan dilakukan hanya satu kali di awal sebelum intervensi. Penjelasan pengenalan alat *virtual reality exergame – Nintendo Switch Ring Fit Adventure* pada kelompok perlakuan dan video latihan senam aerobik lansia pada kelompok kontrol.

Ketiga, pada hari latihan. Partisipan menggunakan baju kaos dan celana olahraga yang nyaman dan tidak ketat, juga sepatu olahraga yang nyaman dan tidak licin. Sebelum dilakukan latihan, partisipan pada kelompok perlakuan dan kelompok kontrol akan melakukan **pemanasan** terlebih dahulu selama 10 menit dengan mengikuti instruktur/video. Begitupun setelah melakukan latihan, partisipan pada kelompok

intervensi dan kelompok kontrol akan melakukan pendinginan selama 10 menit mengikuti instruktur/video.

Setelah itu, kelompok perlakuan berpartisipasi dalam latihan VR *exergame* menggunakan *Nintendo Switch* dengan permainan *Ring Fit Adventure* dengan durasi yang berbeda tiap sesinya di ruangan yang tenang pada bidang yang datar tanpa ada tangga, tidak licin dan tidak ada rintangan. Selama Latihan berlangsung peneliti akan memantau gejala efek samping intervensi yang mungkin dialami partisipan. Jika ada partisipan merasakan gejala efek samping intervensi berupa *cybersickness* (*fatigue*, sakit kepala, mual, susah fokus, berkeringat, atau pusing) maka latihan akan dihentikan dan partisipan akan diberikan penanganan awal sesuai gejala yang dialami. Jika gejala hilang setelah penanganan awal diberikan, partisipan diperbolehkan untuk melanjutkan latihan. Namun bila gejala bertahan selama 30 menit setelah penanganan awal diberikan, maka partisipan akan dibawa ke pelayanan kesehatan terdekat oleh peneliti. Latihan pada kelompok intervensi diberikan selama 6 minggu akan dilakukan 3x latihan/minggu.

Pada kelompok kontrol akan melakukan latihan konvensional menggunakan prosedur senam aerobik yang akan diawasi oleh seorang dokter. Dokter akan mengawasi latihan yang dilakukan oleh partisipan pada kelompok kontrol. Latihan pada kelompok kontrol diberikan selama 6 minggu akan dilakukan 3x latihan/minggu.

Pemantauan kepatuhan latihan termasuk keluhan sebelum, selama, dan setelah latihan, serta pemantauan tingkat intensitas sebelum dan setelah latihan setiap sesi berdasarkan *heart rate reserved*/detak jantung dan RPE akan dicatat dalam *logbook*. Pemantauan ini dilakukan pada kedua kelompok perlakuan dan kontrol.

Keempat, setelah sesi latihan berakhir pada minggu ke-6 akan dilakukan pengambilan data kembali seperti yang dilakukan saat sebelum latihan baik kelompok perlakuan maupun kontrol pada keesokan harinya.

Kami menyadari bahwa dengan mengikuti penelitian ini maka partisipan akan mengorbankan waktu dan tenaga, sehingga kami akan memberikan kompensasi untuk hal tersebut dengan memberikan konsumsi pada setiap sesi setelah latihan. Selama

melakukan latihan ini, anda mungkin akan merasakan lelah sebagai efek samping namun kami akan memberikan waktu yang cukup untuk periode istirahat. Latihan ini memerlukan pemantauan oleh peneliti dan dapat menyebabkan efek samping latihan, sehingga peneliti akan bertanggung jawab penuh untuk hal tersebut. Estimasi waktu yang dibutuhkan setiap pertemuan (sesi latihan) akan meningkat setiap minggu yaitu 40 – 60 menit. Sedangkan estimasi waktu secara keseluruhan untuk semua rangkaian penelitian mulai dari wawancara, pemeriksaan fisik dan pemeriksaan tambahan, hingga latihan adalah 20 jam.

Biaya penelitian ini akan ditanggung oleh dokter yang melakukan penelitian dan tidak dibebankan pada anda. Kami menjamin kerahasiaan semua data pada penelitian ini. Semua hasil pemeriksaan yang terkait dengan penelitian ini akan disampaikan kepada anda secara terbuka.

Kami sangat mengharapkan partisipasi anda, dengan bersedia untuk ikut dalam penelitian ini secara sukarela. Bila anda bersedia, kami berharap anda dapat memberikan persetujuan dalam bentuk lisan dan tertulis.

Bila anda merasa masih ada yang belum jelas atau belum dimengerti dengan baik, anda dapat menanyakan atau minta penjelasan pada saya. Terima kasih.

Penanggung Jawab Penelitian

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Alamat : Perumahan Phinisi Nusantara Residence Blok B No. 5
No. Telepon : 081241493400

Penanggung Jawab Medis

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**KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN UNIVERSITAS HASANUDDIN
RSPTN UNIVERSITAS HASANUDDIN
RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR**



**Sekretariat : Lantai 2 Gedung Laboratorium Terpadu
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SUPPLEMENTARY 2

* informed consent in Indonesian language and approved by human subjects protection review board of hasanuddin university

FORMULIR PERSETUJUAN SETELAH PENJELASAN

Saya yang bertandatangan di bawah ini:

Nama :
Umur :
Pekerjaan :
Pendidikan Terakhir :
Alamat :
No. HP :

setelah mendengar/membaca dan mengerti penjelasan yang diberikan mengenai tujuan, manfaat, dan apa yang akan dilakukan pada penelitian ini, menyatakan setuju untuk ikut dalam penelitian ini secara sukarela tanpa paksaan.

Saya tahu bahwa keikutsertaan saya ini bersifat sukarela tanpa paksaan, sehingga saya bisa menolak ikut atau mengundurkan diri dari penelitian ini. Saya berhak bertanya atau meminta penjelasan pada peneliti bila masih ada hal yang belum jelas atau masih ada hal yang ingin saya ketahui tentang penelitian ini.

Saya juga mengerti bahwa semua biaya yang dikeluarkan sehubungan dengan penelitian ini, akan ditanggung oleh peneliti. Saya percaya bahwa keamanan dan kerahasiaan data penelitian akan terjamin dan saya dengan ini menyetujui semua data saya yang dihasilkan pada penelitian ini untuk disajikan dalam bentuk lisan maupun tulisan.

Dengan membubuhkan tandatangan saya di bawah ini, saya menegaskan keikutsertaan saya secara sukarela dalam studi penelitian ini.

NAMA	TANDA TANGAN	TANGGAL
Partisipan.....
Saksi.....

(Tanda Tangan Saksi diperlukan hanya jika Partisipan tidak dapat memberikan *consent*/persetujuan sehingga menggunakan wali yang sah secara hukum, yaitu untuk partisipan berikut :

1. Berusia di bawah 18 tahun
2. Usia lanjut
3. Gangguan mental
4. Pasien tidak sadar
5. Dan lain-lain kondisi yang tidak memungkinkan memberikan persetujuan

Penanggung Jawab Penelitian :

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Alamat : Perumahan Phinisi Nusantara
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