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Comparing the effects of Fourier M2 robotic rehabilitation machine combined with conventional occupational therapy on hand function and quality of life in patients whose arms have been affected by a recent first stroke

Submission date
24/11/2018

Recruitment status
No longer recruiting

Registration date
28/11/2018

Overall study status
Completed

Last Edited
22/05/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 13/03/2019:
Background and study aims
More than half of stroke patients experience arm problems in their daily lives. These problems limit the ability to do daily life activities with their families resulting in poor quality of life. Different treatments have been tested, including occupational therapy (OT), but their effects are not long-lasting. OT involves helping people to perform daily activities relevant to their life and has been one of the main treatments for stroke for many years. The current challenges with OT treatments include the cost of continued care, high patient time commitment, few OT resources in some hospitals, limited research evidence on new improved methods of OT and that treatment routine ends up exhausting both the therapist and patient.
Robotic machines have been developed and improved over the past 10 years. They can offer patients accurate task-specific intensive treatment with monitored progress. Stroke is varied, which makes it difficult for a therapist to manually provide the right amount of effort needed to produce a treatment effect. Robotic machines might help because they can treat according to personal needs. Robotic machines offer accurate repetitions, graded assistance combined with a variety of simulated tasks which might increase motivation and curiosity in the patient.
Repetition and patient commitment to treatment can speed up their recovery. It might be important to try all kinds of rehabilitation treatment in the first 3 months after stroke to have the best chance of recovery.
Combining OT with other treatments might help stroke patients to recover and not lose hope in their future. There might be promising positive results if Fourier M2 and OT are combined to treat arms of stroke patients, especially in the first 3 months after their first stroke. This study will try to see if there is a good result after combining OT and Fourier M2 robotic machine to improve arm function and quality of life of stroke patients.

Who can participate?
People aged 45-75 years who have had first-time stroke within the last 2 months and can understand the Chinese language.

What does the study involve?
Participants will be randomly allocated to one of two groups. Participants in both groups will follow an OT program for 6 weeks. During the day, the patient will do some hand and arm exercises and have their arm moved by the therapist in two sessions of 40 minutes. The participants in the treatment group will follow the same program except that instead of the second daytime session, they will use the Fourier robotic rehabilitation machine to play a game involving harvesting fruits and vegetables.

What are the possible benefits and risks of participating?
The therapist and a nurse will be asked to monitor the patient while engaging in assessment and treatment procedures. As they engage in treatment, nurse will monitor and record the patient's vital signs while therapist will track any adverse events resulting from treatment and any fatigue signs. Once any negative side effect is observed from patient, it will be recorded then taken care of immediately and treatment will be stopped. The treatment area will be made clean, all electrical equipment not used for the study will be removed and air conditioner will be controlled to meet patient's needs prior to assessment and treatment.
In this study, there will be no risks, as all of the study instruments have no potential harm to the patient's body. All equipment to be used are standard equipment and will not cause any injury to the patient. Since the patient is hospitalized, special care will be provided to the patient and a standby nurse will be present to monitor vital signs before and after treatment.
The potential benefits are that the patient might regain more function in their arm or regain function more quickly in the treatment group. The therapy might help patients to work towards active movement and learn to stabilize objects as primary goal of stages 1 to 4 (updated 21/05 /2019, previously: 1 to 2) Brunnstrom recovery stages. The therapy encourages repetitive use of the affected arm and using both arms in functional activities. It encourages body awareness. The therapy is not expensive and the robot is user-friendly and safe.All patients will receive standard OT as usual.

Where is the study run from?
Xuzhou Rehabilitation Hospital (China)

When is the study starting and how long is it expected to run for?
February 2018 to October 2019

Who is funding the study?
Jiangsu Youth Medical Talent Fund and Xuzhou City Medical Young Reserve Talents Project

Who is the main contact?
Bianca Chinembiri, biamachinez@gmail.com

Previous plain English summary as of 01/03/2019:
Background and study aims
More than half of stroke patients experience arm problems in their daily lives. These problems limit the ability to do daily life activities with their families resulting in poor quality of life. Different treatments have been tested, including occupational therapy (OT), but their effects are not long-lasting. OT involves helping people to perform daily activities relevant to their life and has been one of the main treatments for stroke for many years. The current challenges with OT treatments include the cost of continued care, high patient time commitment, few OT

resources in some hospitals, limited research evidence on new improved methods of OT and that treatment routine ends up exhausting both the therapist and patient.
Robotic machines have been developed and improved over the past 10 years. They can offer patients accurate task-specific intensive treatment with monitored progress. Stroke is varied, which makes it difficult for a therapist to manually provide the right amount of effort needed to produce a treatment effect. Robotic machines might help because they can treat according to personal needs. Robotic machines offer accurate repetitions, graded assistance combined with a variety of simulated tasks which might increase motivation and curiosity in the patient. Repetition and patient commitment to treatment can speed up their recovery. It might be important to try all kinds of rehabilitation treatment in the first 3 months after stroke to have the best chance of recovery.
Combining OT with other treatments might help stroke patients to recover and not lose hope in their future. There might be promising positive results if Fourier M2 and OT are combined to treat arms of stroke patients, especially in the first 3 months after their first stroke. This study will try to see if there is a good result after combining OT and Fourier M2 robotic machine to improve arm function and quality of life of stroke patients.

Who can participate?
People aged 45-75 years who have had first-time stroke within the last 2 months and can understand the Chinese language.

What does the study involve?
Participants will be randomly allocated to one of two groups. Participants in both groups will follow an OT program for 6 weeks. During the day, the patient will do some hand and arm exercises and have their arm moved by the therapist in two sessions of 40 minutes. The participants in the treatment group will follow the same program except that instead of the second daytime session, they will use the Fourier robotic rehabilitation machine to play a game involving harvesting fruits and vegetables.

What are the possible benefits and risks of participating?
The therapist and a nurse will be asked to monitor the patient while engaging in assessment and treatment procedures. As they engage in treatment, nurse will monitor and record the patient’s vital signs while therapist will track any adverse events resulting from treatment and any fatigue signs. Once any negative side effect is observed from patient, it will be recorded then taken care of immediately and treatment will be stopped. The treatment area will be made clean, all electrical equipment not used for the study will be removed and air conditioner will be controlled to meet patient’s needs prior to assessment and treatment.
In this study, there will be no risks, as all of the study instruments have no potential harm to the patient's body. All equipment to be used are standard equipment and will not cause any injury to the patient. Since the patient is hospitalized, special care will be provided to the patient and a standby nurse will be present to monitor vital signs before and after treatment.
The potential benefits are that the patient might regain more function in their arm or regain function more quickly in the treatment group. All patients will receive standard OT as usual.

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Jiangsu Youth Medical Talent Fund and Xuzhou City Medical Young Reserve Talents Project

Who is the main contact?
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Previous plain English summary as of 03/12/2018:
Background and study aims
More than half of stroke patients experience arm problems in their daily lives. These problems limit the ability to do daily life activities with their families resulting in poor quality of life. Different treatments have been tested, including occupational therapy (OT), but their effects are not long-lasting. OT involves helping people to perform daily activities relevant to their life and has been one of the main treatments for stroke for many years. The current challenges with OT treatments include the cost of continued care, high patient time commitment, few OT resources in some hospitals, limited research evidence on new improved methods of OT and that treatment routine ends up exhausting both the therapist and patient.
Robotic machines have been developed and improved over the past 10 years. They can offer patients accurate task-specific intensive treatment with monitored progress. Stroke is varied, which makes it difficult for a therapist to manually provide the right amount of effort needed to produce a treatment effect. Robotic machines might help because they can treat according to personal needs. Robotic machines offer accurate repetitions, graded assistance combined with a variety of simulated tasks which might increase motivation and curiosity in the patient. Repetition and patient commitment to treatment can speed up their recovery. It might be important to try all kinds of rehabilitation treatment in the first 3 months after stroke to have the best chance of recovery.
Combining OT with other treatments might help stroke patients to recover and not lose hope in their future. There might be promising positive results if Fourier M2 and OT are combined to treat arms of stroke patients, especially in the first 3 months after their first stroke. This study will try to see if there is a good result after combining OT and Fourier M2 robotic machine to improve arm function and quality of life of stroke patients.

Who can participate?
People aged 30-90 years who have had first-time stroke within the last 3 months and can understand the Chinese language.

What does the study involve?
Participants will be randomly allocated to one of two groups. Participants in both groups will follow an OT program for 6 weeks. During the day, the patient will do some hand and arm exercises and have their arm moved by the therapist in two sessions of 30 minutes. During the evening, when they are in the ward, the participants will spend 30 minutes practicing daily activities such as brushing teeth, opening a water bottle and taking off clothes with buttons, zippers etc. The participants in the treatment group will follow the same program except that instead of the second daytime session, they will use the Fourier robotic rehabilitation machine to play a game involving harvesting fruits and vegetables.

What are the possible benefits and risks of participating?
The therapist and a nurse will be asked to monitor the patient while engaging in assessment and treatment procedures. As they engage in treatment, nurse will monitor and record the patient's vital signs while therapist will track any adverse events resulting from treatment and any fatigue signs. Once any negative side effect is observed from patient, it will be recorded then taken care of immediately and treatment will be stopped. The treatment area will be made clean, all electrical equipment not used for the study will be removed and air conditioner will be controlled to meet patient's needs prior to assessment and treatment.
In this study, there will be no risks, as all of the study instruments have no potential harm to the

patient's body. All equipment to be used are standard equipment and will not cause any injury to the patient. Since the patient is hospitalized, special care will be provided to the patient and a standby nurse will be present to monitor vital signs before and after treatment.
The potential benefits are that the patient might regain more function in their arm or regain function more quickly in the treatment group. All patients will receive standard OT as usual.

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Robotic machines have been developed and improved over the past 10 years. They can offer patients accurate task-specific intensive treatment with monitored progress. Stroke is varied, which makes it difficult for a therapist to manually provide the right amount of effort needed to produce a treatment effect. Robotic machines might help because they can treat according to personal needs. Robotic machines offer accurate repetitions, graded assistance combined with a variety of simulated tasks which might increase motivation and curiosity in the patient. Repetition and patient commitment to treatment can speed up their recovery. It might be important to try all kinds of rehabilitation treatment in the first 3 months after stroke to have the best chance of recovery.
Combining OT with other treatments might help stroke patients to recover and not lose hope in their future. Kinesiotaping is a treatment which can be used to hold muscles that are weak or out of position so that the arm is able to move without feeling floppy or loose. In this study Kinesiotaping can be done on the patients' shoulder to assist the shoulder muscles while they do OT and Fourier M2 (robotic machine) activities. There might be promising positive results if Kinesiotaping, Fourier M2 and OT are combined to treat arms of stroke patients, especially in the first 3 months after their first stroke. This study will try to see if there is a good result after combining OT, Fourier M2 robotic machine and Kinesiotaping to improve arm function and quality of life of stroke patients.

Who can participate?
People aged 30-90 years who have had first-time stroke within the last 3 months and can understand the Chinese language.

What does the study involve?
Participants will be randomly allocated to one of two groups. Participants in both groups will follow an OT program for 6 weeks. During the day, the patient will do some hand and arm exercises and have their arm moved by the therapist in two sessions of 30 minutes. During the evening, when they are in the ward, the participants will spend 30 minutes practicing daily activities such as brushing teeth, opening a water bottle and taking off clothes with buttons, zippers etc. The participants in the treatment group will follow the same program except that instead of the second daytime session, they will have Kinesiotherapy tape applied to their arms and will use the Fourier robotic rehabilitation machine to play a game involving harvesting fruits and vegetables.

What are the possible benefits and risks of participating?
The therapist and a nurse will be asked to monitor the patient while engaging in assessment and treatment procedures. As they engage in treatment, nurse will monitor and record the patient's vital signs while therapist will track any adverse events resulting from treatment and any fatigue signs. Once any negative side effect is observed from patient, it will be recorded then taken care of immediately and treatment will be stopped. The treatment area will be made clean, all electrical equipment not used for the study will be removed and air conditioner will be controlled to meet patient's needs prior to assessment and treatment.
In this study, there will be no risks, as all of the study instruments have no potential harm to the patient's body. All equipment to be used are standard equipment and will not cause any injury to the patient. Since the patient is hospitalized, special care will be provided to the patient and a standby nurse will be present to monitor vital signs before and after treatment.
The potential benefits are that the patient might regain more function in their arm or regain function more quickly in the treatment group. All patients will receive standard OT as usual.

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Who is the main contact?
Bianca Chinembiri, biamachinez@gmail.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
The Fourier M2 Robot Machine versus Occupational Therapy on Post-stroke Upper Limb Function and Independence-related Quality of Life: A Randomized Clinical Trial

Acronym
FM2OTKT

Study objectives
Current hypotheses as of 03/12/2018:
Null Hypothesis: We hypothesize that if Fourier M2 robotic machine and Occupational Therapy treatments are combined, they have no effect on promoting upper limb function recovery and quality of life of post-stroke patients.
Research Hypothesis: I hypothesize that if Fourier M2 and Occupational therapy treatments are combined, they may have an effect upon upper limb function recovery and quality of life of post-stroke patients.

Previous hypotheses:
Null Hypothesis: We hypothesize that if Fourier M2 robotic machine coupled with Kinesiotaping and Occupational Therapy treatments are combined, they have no effect on promoting upper limb function recovery and quality of life of post-stroke patients.
Research Hypothesis: I hypothesize that if Fourier M2 coupled with Kinesio-taping and Occupational therapy treatments are combined, they may have an effect upon upper limb function recovery and quality of life of post-stroke patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Xuzhou Rehabilitation Hospital Biomedical Ethics Review Committee, 19/11/2018, no reference number available.

Primary study design
Interventional

Study design
Parallel-arm randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Shoulder and elbow function of affected upper limbs of stroke patients

Interventions
Current intervention as of 18/06/2019:
Allocation and blinding:
Blinding in this study will be partial. The control group will be blinded from the treatment whereas blinding will not be feasible in the treatment group due to the nature of their allocated treatment. The treating occupational therapist (OT) will be not aware of the data from the outcome measures evaluated by the blinded investigator to the group assignment. The patients will be blinded to the treatment provided to the other group. Randomization will be done using a random number table. The allocation ratio will be 1:1. To assess the blinding efficiency, the investigator will answer a question related to their opinion on the allocation after each of the follow-up evaluations. The participants will also be asked after the study which group they think they were allocated to ensure blinding was correctly done.

Randomization and matching:
The sampling method for this study will be stratified block randomization. Every one participant has an equal chance of being selected in to the study. It is ideal because it ensures that the outcomes of the study are due to the manipulation of the independent variable and are not influenced by the composition of the study groups. It further restricts the chances of imbalances or poor matching to ensure treatment groups are as alike as possible for prognostic variables and other patient factors. The randomization of participant's treatment numbers in this study will be done by an independent staff member not part of the study, using random number tables or use of a computer that generates random numbers prior to the beginning of the study. The randomization block size will be 4. We will enroll the first 4 new patients in the first week and the last 4 new patients in the second week. Randomization will be stratified by sex and age given that it is unknown if they influence the physiological responses to the rehabilitation treatment. There will be 4 strata as follows:
Gender = Male or Female
Age (years) = 45-55 or 56-75

Recruitment of participants:
The recruitment of participants will be done shortly after they have given consent and volunteered to join the study. Each patient in each group will be given an informed consent form in Chinese to inform them about the research. If they agree to participate, they sign the forms and get a copy to keep. Their eligibility criteria will be assessed and a few demographic details will be recorded before the outcome measures of the study are used to evaluate them.

Interventions:
Both the treatment and control groups will attend a structured Occupational Therapy (OT) program for a duration of 6 weeks. This program will take 60 minutes per day, 5 days a week and in a period of 6 weeks. OT treatment of both groups will be based on the Brunnstrom's treatment principles for stroke patients in stage 1 to 4 of motor recovery of the upper limb. They will also have similar evaluations similar to the other group which consists of baseline and after 6 weeks' evaluations using the BRS, BI and FMA-UE assessment instruments.

Control group:
1. An OT program for 50 minutes during the day, 5 days a week for 6 weeks:
1.1. First 10 minutes: Self-Range of motion and passive stretch exercises for the shoulder, elbow, wrist, thumb joints and muscles. Movements include:
1.1.1. Shoulder extension, flexion, abduction and adduction
1.1.2. Elbow extension and flexion
1.1.3. Pronation and supination
1.1.4. Wrist flexion, extension, ulnar and radial deviations
1.1.5. Metacarpophalangeal (MCP) joint flexion and extension
1.1.6. Thumb flexion, extension and opposition
2. Second 40 minutes
Patients can use OT equipment in the training room depending on their stage of Brunnstrom recovery.
Brunnstrom stage 1 and 2: Treatment will be targeted at facilitating range of motion and repetitive use of the upper limb joints and muscles. Using equipment such as shoulder arc board, shoulder exercise ladder and inclined sanding board.
Brunnstrom stage 3 and 4: Treatment will be targeted at facilitating voluntary and co-ordinated active movements of the upper limb joints and muscles. Using equipment such as finger ladder, semi-circular peg board and training in dressing.

Treatment group:
1. Their treatment will be 60 min. The first 40 min are similar to the control group.
2. During the last 20 min, each patient will have to harvest fruits and vegetables displayed on the screen. The settings on the the Fourier M2 robotic rehabilitation machine will be:
2.1. Treatment mode in assistive mode
2.2. Task will be game number 1 of harvesting fruits and vegetables
2.3. Middle activity range button with assistance at level 3
2.4. Path of movement will be level 3
2.5. Time for activity will be set for 20 min
3. Upper limb movements on the robot will consist of:
3.1. Shoulder horizontal abduction and adduction
3.2. Elbow flexion, extension and forearm partial pronation
3.3. Wrist neutral position
3.4. MCP flexion
3.5. Thumb opposition
The following will be recorded; activity accomplishment time in min and s, total length of movements in m, speed of movement in m/s, energy consumption in kcal, presence/absence of spasms.
If a spasm occurs, there is an emergency red button that can be pressed to stop the activity.

Previous intervention as of 21/05/2019:
Allocation and blinding:
Blinding in this study will be partial. The control group will be blinded from the treatment whereas blinding will not be feasible in the treatment group due to the nature of their allocated treatment. The treating occupational therapist (OT) will be not aware of the data from the outcome measures evaluated by the blinded investigator to the group assignment. The patients will be blinded to the treatment provided to the other group. Randomization will be done using a random number table. The allocation ratio will be 1:1. To assess the blinding efficiency, the investigator will answer a question related to their opinion on the allocation after each of the follow-up evaluations. The participants will also be asked after the study which group they think they were allocated to ensure blinding was correctly done.

Randomization and matching:
The sampling method for this study will be stratified block randomization. Every one participant has an equal chance of being selected in to the study. It is ideal because it ensures that the outcomes of the study are due to the manipulation of the independent variable and are not influenced by the composition of the study groups. It further restricts the chances of imbalances or poor matching to ensure treatment groups are as alike as possible for prognostic variables and other patient factors. The randomization of participant's treatment numbers in this study will be done by an independent staff member not part of the study, using random number tables or use of a computer that generates random numbers prior to the beginning of the study. The randomization block size will be 4. We will enroll the first 4 new patients in the first week and the last 4 new patients in the second week. Randomization will be stratified by sex and age given that it is unknown if they influence the physiological responses to the rehabilitation treatment. There will be 4 strata as follows:
Gender = Male or Female
Age (years) = 45-55 or 56-75

Recruitment of participants:
The recruitment of participants will be done shortly after they have given consent and volunteered to join the study. Each patient in each group will be given an informed consent form in Chinese to inform them about the research. If they agree to participate, they sign the forms and get a copy to keep. Their eligibility criteria will be assessed and a few demographic details will be recorded before the outcome measures of the study are used to evaluate them.

Interventions:
Both the treatment and control groups will attend a structured Occupational Therapy (OT) program for a duration of 6 weeks. This program will take 60 minutes per day, 5 days a week and in a period of 6 weeks. OT treatment of both groups will be based on the Brunnstrom's treatment principles for stroke patients in stage 1 and 2 of motor recovery of the upper limb. They will also have similar evaluations similar to the other group which consists of baseline and after 6 weeks' evaluations using the BRS, BI and FMA-UE assessment instruments.

Control group:
1. An OT program for 50 minutes during the day, 5 days a week for 6 weeks:
1.1. First 10 minutes: Self-Range of motion and passive stretch exercises for the shoulder, elbow, wrist, thumb joints and muscles. Movements include:
1.1.1. Shoulder extension, flexion, abduction and adduction
1.1.2. Elbow extension and flexion
1.1.3. Pronation and supination
1.1.4. Wrist flexion, extension, ulnar and radial deviations
1.1.5. Metacarpophalangeal (MCP) joint flexion and extension
1.1.6. Thumb flexion, extension and opposition
2. Next 40 minutes
Thick wooden pegboard sticks will be carried from the left to right/right to left side using both hands attached together at shoulder level into a plastic dish. The plastic dish will be placed at the right side, then the left side and finally the midline on a table.
After that, the patient will also use both hands to lift different puzzle pieces and place them on the puzzle board. The hands should be lifted to shoulder level.

Treatment group:
1. Their treatment will be 60 min. The first 40 min are similar to the control group.
2. During the last 20 min, each patient will have to harvest fruits and vegetables displayed on the screen. The settings on the the Fourier M2 robotic rehabilitation machine will be:

2.1. Treatment mode in assistive mode
2.2. Task will be game number 1 of harvesting fruits and vegetables
2.3. Middle activity range button with assistance at level 3
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3.1. Shoulder horizontal abduction and adduction
3.2. Elbow flexion, extension and forearm partial pronation
3.3. Wrist neutral position
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3.5. Thumb opposition
The following will be recorded; activity accomplishment time in min and s, total length of movements in m, speed of movement in m/s, energy consumption in kcal, presence/absence of spasms.
If a spasm occurs, there is an emergency red button that can be pressed to stop the activity.

Previous intervention as of 13/03/2019:
Allocation and blinding:
Blinding in this study will be partial. The control group will be blinded from the treatment whereas blinding will not be feasible in the treatment group due to the nature of their allocated treatment. The treating occupational therapist (OT) will be not aware of the data from the outcome measures evaluated by the blinded investigator to the group assignment. The patients will be blinded to the treatment provided to the other group. Randomization will be done using a random number table. The allocation ratio will be 1:1. To assess the blinding efficiency, the investigator will answer a question related to their opinion on the allocation after each of the follow-up evaluations. The participants will also be asked after the study which group they think they were allocated to ensure blinding was correctly done.

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Interventions:
Both the treatment and control groups will attend a structured Occupational Therapy (OT) program for a duration of 6 weeks. This program will take 40 minutes per day, 5 days a week and in a period of 6 weeks. OT treatment of both groups will be based on the Brunnstrom's treatment principles for stroke patients in stage 1 and 2 of motor recovery of the upper limb. They will also have similar evaluations similar to the other group which consists of baseline, 4 weeks' and 6 weeks' evaluations using the TMS, BRS, SSQOL and FMA-UE assessment instruments.

Control group:
1. An OT program for 40 minutes during the day, 5 days a week for 6 weeks:
1.1. First 10 minutes: Self-Range of motion and passive stretch exercises for the shoulder, elbow, wrist, thumb joints and muscles. Movements include:
1.1.1. Shoulder extension, flexion, abduction and adduction
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1.1.5. Metacarpophalangeal (MCP) joint flexion and extension
1.1.6. Thumb flexion, extension and opposition
2. Next 30 minutes
Thick wooden pegboard sticks will be carried from the left to right/right to left side using both hands attached together at shoulder level into a plastic dish. The plastic dish will be placed at the right side, then the left side and finally the midline on a table.
After that, the patient will also use both hands to lift different puzzle pieces and place them on the puzzle board. The hands should be lifted to shoulder level.

Treatment group:
1. Their treatment will be 50 min. The first 10 min and next 30 min are similar to the control group.
2. During the last 10 min, each patient will have to harvest fruits and vegetables displayed on the screen. The settings on the the Fourier M2 robotic rehabilitation machine will be:
2.1. Treatment mode in assistive mode
2.2. Task will be game number 1 of harvesting fruits and vegetables
2.3. Middle activity range button with assistance at level 3
2.4. Path of movement will be level 3
2.5. Time for activity will be set for 10 min
3. Upper limb movements on the robot will consist of:
3.1. Shoulder horizontal abduction and adduction
3.2. Elbow flexion, extension and forearm partial pronation
3.3. Wrist neutral position
3.4. MCP flexion
3.5. Thumb opposition
The following will be recorded; activity accomplishment time in min and s, total length of movements in m, speed of movement in m/s, energy consumption in kcal, presence/absence of spasms.
If a spasm occurs, there is an emergency red button that can be pressed to stop the activity.

Previous intervention as of 01/03/2019:
Allocation and blinding:
Blinding in this study will be partial. The control group will be blinded from the treatment whereas blinding will not be feasible in the treatment group due to the nature of their allocated treatment. The treating occupational therapist (OT) will be not aware of the data from the

outcome measures evaluated by the blinded investigator to the group assignment. The patients will be blinded to the treatment provided to the other group. Randomization will be done using a random number table. The allocation ratio will be 1:1. To assess the blinding efficiency, the investigator will answer a question related to their opinion on the allocation after each of the follow-up evaluations. The participants will also be asked after the study which group they think they were allocated to ensure blinding was correctly done.

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Age (years) = 45-55 or 56-75

Recruitment of participants:
The recruitment of participants will be done shortly after they have given consent and volunteered to join the study. Each patient in each group will be given an informed consent form in Chinese to inform them about the research. If they agree to participate, they sign the forms and get a copy to keep. Their eligibility criteria will be assessed and a few demographic details will be recorded before the outcome measures of the study are used to evaluate them.

Interventions:
Both the treatment and control groups will attend a structured Occupational Therapy (OT) program for a duration of 6 weeks. This program will take 40 minutes per day, 5 days a week and in a period of 6 weeks. OT treatment of both groups will be based on the Brunnstrom's treatment principles for stroke patients in stage 1 and 2 of motor recovery of the upper limb. They will also have similar evaluations similar to the other group which consists of baseline, 4 weeks' and 6 weeks' evaluations using the TMS, BRS, SSQOL and FMA-UE assessment instruments.

Control group:
1. Daytime activity:
1.1. First 30 minutes
Self-Range of motion and passive stretch exercises for the shoulder, elbow, wrist and thumb joints and muscles respectively according to Chart A. The rules of these exercises include keeping movements slow and controlled and to avoid rapid and jerky movements. The patient should hold each position for at least 5 seconds, or as indicated by the therapist. The patient must not force the movement. Exercises will cause a stretch but should not cause sharp pain. If exercises cause sharp pain, the patient must stop. This should be done 5 repetitions in each exercise activity and grading from large muscles and joints to small muscles and joints.
1.2. Second 10 minutes

Therapist uses proprioceptive and exteroceptive stimuli to elicit stretch reflexes such as quick stretch of agonist muscles 5 times and massaging of skin surface of the affected upper limb to facilitate movement responses 5 times.

Treatment group:
The treatment for the Treatment group will have same OT as control group, but with the Fourier M2 robotic rehabilitation machine. This will also take 40 minutes.
3. Daytime activity:
3.1. First 30 minutes:
Same as control group procedures.
3.2. Second 10 minutes
Same as control group procedures.
3.3. Third 10 minutes
Each patient will sit on the Fourier M2 robotic machine and use the handle assisted by therapist to pull/push to guide their upper limbs on the task given (harvesting fruits and vegetables displayed on the screen). The settings on the machine will be:
3.3.1. Treatment mode in assistive mode.
3.3.2. Task will be game number 1 of harvesting fruits and vegetables.
3.3.3. Middle activity range button with assistance at level 3.
3.3.4. Path of movement will be level 3.
3.3.5. Time for activity will be set for 10 minutes.
The following will be recorded; activity accomplishment time in minutes and seconds, total length of movements in metres, speed of movement in metres/second, energy consumption in kilocalories, presence/absence of spasms.
If a spasm occurs, there is an emergency red button that can be pressed to stop the activity.

Previous intervention as of 18/01/2019:
Allocation and blinding:
Blinding in this study will be partial. The control group will be blinded from the treatment whereas blinding will not be feasible in the treatment group due to the nature of their allocated treatment. The treating occupational therapist (OT) will be not aware of the data from the outcome measures evaluated by the blinded investigator to the group assignment. The patients will be blinded to the treatment provided to the other group. Randomization will be done using a random number table. The allocation ratio will be 1:1. To assess the blinding efficiency, the investigator will answer a question related to their opinion on the allocation after each of the follow-up evaluations. The participants will also be asked after the study which group they think they were allocated to ensure blinding was correctly done.

Randomization and matching:
The sampling method for this study will be stratified block randomization. Every one participant has an equal chance of being selected in to the study. It is ideal because it ensures that the outcomes of the study are due to the manipulation of the independent variable and are not influenced by the composition of the study groups. It further restricts the chances of imbalances or poor matching to ensure treatment groups are as alike as possible for prognostic variables and other patient factors. The randomization of participant's treatment numbers in this study will be done by an independent staff member not part of the study, using an online website called www.randomizer.org or use of a computer that generates random numbers prior to the beginning of the study. The randomization block size will be 4. We will enroll the first 4 new patients in the first week and the last 4 new patients in the second week. Randomization will be stratified by sex and age given that it is unknown if they influence the physiological responses to

the rehabilitation treatment. There will be 6 strata as follows:
Gender = Male or Female
Age (years) = <40, 41-59, >60

Recruitment of participants:
The recruitment of participants will be done shortly after they have given consent and volunteered to join the study. Each patient in each group will be given an informed consent form in Chinese to inform them about the research. If they agree to participate, they sign the forms and get a copy to keep. Their eligibility criteria will be assessed and a few demographic details will be recorded before the outcome measures of the study are used to evaluate them.

Interventions:
Both the treatment and control groups will attend a structured Occupational Therapy (OT) program for a duration of 6 weeks. This program will take 40 minutes per day, 5 days a week and in a period of 6 weeks. OT treatment of both groups will be based on the Brunnstrom's treatment principles for stroke patients in stage 1 and 2 of motor recovery of the upper limb. They will also have similar evaluations similar to the other group which consists of baseline, 4 weeks' and 6 weeks' evaluations using the TMS, BRS, SSQOL and FMA-UE assessment instruments.

Control group:
1. Daytime activity:
1.1. First 30 minutes
Self-Range of motion and passive stretch exercises for the shoulder, elbow, wrist and thumb joints and muscles respectively according to Chart A. The rules of these exercises include keeping movements slow and controlled and to avoid rapid and jerky movements. The patient should hold each position for at least 5 seconds, or as indicated by the therapist. The patient must not force the movement. Exercises will cause a stretch but should not cause sharp pain. If exercises cause sharp pain, the patient must stop. This should be done 5 repetitions in each exercise activity and grading from large muscles and joints to small muscles and joints.
1.2. Second 10 minutes
Therapist uses proprioceptive and exteroceptive stimuli to elicit stretch reflexes such as quick stretch of agonist muscles 5 times and brushing of skin surface of the affected upper limb to facilitate movement responses 5 times. Patient can practice isometric muscle contractions of the shoulder and elbow on a stabilized surface like a small table for 5 repetitions each.

Treatment group:
The treatment for the Treatment group will have same OT as control group, but with the Fourier M2 robotic rehabilitation machine. This will also take 40 minutes.
3. Daytime activity:
3.1. First 30 minutes:
Same as control group procedures.
3.2. Second 10 minutes
Same as control group procedures.
3.3. Third 10 minutes
Each patient will sit on the Fourier M2 robotic machine and use the handle assisted by therapist to pull/push to guide their upper limbs on the task given (harvesting fruits and vegetables displayed on the screen). The settings on the machine will be:
3.3.1. Treatment mode in assistive mode.
3.3.2. Task will be game number 1 of harvesting fruits and vegetables.
3.3.3. Middle activity range button with assistance at level 3.
3.3.4. Path of movement will be level 3.

3.3.5. Time for activity will be set for 10 minutes.
The following will be recorded; activity accomplishment time in minutes and seconds, total length of movements in metres, speed of movement in metres/second, energy consumption in kilocalories, presence/absence of spasms.
If a spasm occurs, there is an emergency red button that can be pressed to stop the activity.

Previous intervention as of 03/12/2018:
Allocation and blinding:
Blinding in this study will be partial. The control group will be blinded from the treatment whereas blinding will not be feasible in the treatment group due to the nature of their allocated treatment. The treating occupational therapist (OT) will be not aware of the data from the outcome measures evaluated by the blinded investigator to the group assignment. The patients will be blinded to the treatment provided to the other group. Randomized numbers will be printed and put in opaque envelopes by a staff member who is not part of the research team. The participants who agree to participate in the study will be asked to give consent first. Then they receive at random one of the shuffled sealed envelopes with sequential numeric treatment allocations inside, which will be opened by the OT at the first treatment session. The allocation ratio will be 1:1. To assess the blinding efficiency, the investigator will answer a question related to their opinion on the allocation after each of the follow-up evaluations. The participants will also be asked after the study which group they think they were allocated to ensure blinding was correctly done.

Randomization and matching:
The sampling method for this study will be stratified block randomization. Every one participant has an equal chance of being selected in to the study. It is ideal because it ensures that the outcomes of the study are due to the manipulation of the independent variable and are not influenced by the composition of the study groups. It further restricts the chances of imbalances or poor matching to ensure treatment groups are as alike as possible for prognostic variables and other patient factors. The randomization of participant's treatment numbers in this study will be done by an independent staff member not part of the study, using an online website called www.randomizer.org or use of a computer that generates random numbers prior to the beginning of the study. The randomization block size will be 4. We will enroll the first 4 new patients in the first week and the last 4 new patients in the second week. Randomization will be stratified by sex and age given that it is unknown if they influence the physiological responses to the rehabilitation treatment. There will be 6 strata as follows:
Gender = Male or Female
Age (years) = <40, 41-59, >60

Recruitment of participants:
The recruitment of participants will be done shortly after they have given consent and volunteered to join the study. Each patient in each group will be given an informed consent form in Chinese to inform them about the research. If they agree to participate, they sign the forms and get a copy to keep. Their eligibility criteria will be assessed and a few demographic details will be recorded before the outcome measures of the study are used to evaluate them.

Interventions:
Both the treatment and control groups will attend a structured Occupational Therapy (OT) program for a duration of 6 weeks. This program will take 40 minutes in the day and 30 minutes night time treatment per day, 5 days a week and in a period of 6 weeks. OT treatment of both groups will be based on the Brunnstrom's treatment principles for stroke patients in stage 1 and

2 of motor recovery of the upper limb. They will also have similar evaluations similar to the other group which consists of baseline, 4 weeks' and 6 weeks' evaluations using the TMS, BRS, SSQOL and FMA-UE assessment instruments.

Control group:
1. Daytime activity:
1.1. First 30 minutes
Self-Range of motion and passive stretch exercises for the shoulder, elbow, wrist and thumb joints and muscles respectively according to Chart A. The rules of these exercises include keeping movements slow and controlled and to avoid rapid and jerky movements. The patient should hold each position for at least 5 seconds, or as indicated by the therapist. The patient must not force the movement. Exercises will cause a stretch but should not cause sharp pain. If exercises cause sharp pain, the patient must stop. This should be done 5 repetitions in each exercise activity and grading from large muscles and joints to small muscles and joints.
1.2. Second 10 minutes
Therapist uses proprioceptive and exteroceptive stimuli to elicit stretch reflexes such as quick stretch of agonist muscles 5 times and brushing of skin surface of the affected upper limb to facilitate movement responses 5 times. Patient can practice isometric muscle contractions of the shoulder and elbow on a stabilized surface like a small table for 5 repetitions each.
2. Night time treatment in the ward (30 minutes):
Each patient engages in the tasks written on the Activity Task Checklist which has a set of daily activities which require learning stabilization of objects using the affected upper limb. The patient is allowed to have rest breaks in between the activities when they feel tired. He or she can include other activities they want and incorporate the affected hand into the activities. The caregiver can write down the extra activities done by the patient if present so that they can be listed on the patient's prescription of daily task activities. The caregiver will be able to tick on the checklist when the activity has been done. As the patient does the activity, the caregiver can encourage bilateral use of hands and focus on stabilization and manipulation of objects using the affected hand.
Monday = Task 1-2
Tuesday = Task 3-4
Wednesday = Task 5-6
Thursday = Task 7-8
Friday = Task 1-2
Materials required for the tasks on the checklist:
Toothpaste and tooth brush
Books or newspapers
Clothes with zipper or buttons
Water bottle
Hair brush
Plate and food

Treatment group:
The treatment for the Treatment group will have same OT as control group, but with the Fourier M2 robotic rehabilitation machine. This will also take 40 minutes during the day and 30 minutes during the night.
3. Daytime activity:
3.1. First 30 minutes:
Same as control group procedures.
3.2. Second 10 minutes
Each patient will sit on the Fourier M2 robotic machine and use the handle assisted by therapist to pull/push to guide their upper limbs on the task given (harvesting fruits and vegetables

displayed on the screen). The machine will have similar settings for patients in this group in the passive movement training mode. The machine will record factors such as the range of motion, moving trajectory and muscle strength.
4. Night time treatment in the ward (30 minutes):
Same as control group procedures.

Previous intervention:
Allocation and blinding:
Blinding in this study will be partial. The control group will be blinded from the treatment whereas blinding will not be feasible in the treatment group due to the nature of their allocated treatment. The treating occupational therapist (OT) will be not aware of the data from the outcome measures evaluated by the blinded investigator to the group assignment. The patients will be blinded to the treatment provided to the other group. Randomized numbers will be printed and put in opaque envelopes by a staff member who is not part of the research team. The participants who agree to participate in the study will be asked to give consent first. Then they receive at random one of the shuffled sealed envelopes with sequential numeric treatment allocations inside, which will be opened by the OT at the first treatment session. The allocation ratio will be 1:1. To assess the blinding efficiency, the investigator will answer a question related to their opinion on the allocation after each of the follow-up evaluations. The participants will also be asked after the study which group they think they were allocated to ensure blinding was correctly done.

Randomization and matching:
The sampling method for this study will be stratified block randomization. Every one participant has an equal chance of being selected in to the study. It is ideal because it ensures that the outcomes of the study are due to the manipulation of the independent variable and are not influenced by the composition of the study groups. It further restricts the chances of imbalances or poor matching to ensure treatment groups are as alike as possible for prognostic variables and other patient factors. The randomization of participant's treatment numbers in this study will be done by an independent staff member not part of the study, using an online website called www.randomizer.org or use of a computer that generates random numbers prior to the beginning of the study. The randomization block size will be 4. We will enroll the first 4 new patients in the first week and the last 4 new patients in the second week. Randomization will be stratified by sex and age given that it is unknown if they influence the physiological responses to the rehabilitation treatment. There will be 6 strata as follows:
Gender = Male or Female
Age (years) = <40, 41-59, >60

Recruitment of participants:
The recruitment of participants will be done shortly after they have given consent and volunteered to join the study. Each patient in each group will be given an informed consent form in Chinese to inform them about the research. If they agree to participate, they sign the forms and get a copy to keep. Their eligibility criteria will be assessed and a few demographic details will be recorded before the outcome measures of the study are used to evaluate them.

Interventions:
Both the treatment and control groups will attend a structured Occupational Therapy (OT) program for a duration of 6 weeks. This program will take 1 hour in the day and 30 minutes night time treatment per day, 5 days a week and in a period of 6 weeks. OT treatment of both groups will be based on the Brunnstrom's treatment principles for stroke patients in stage 1 and 2 of

motor recovery of the upper limb. They will also have similar evaluations similar to the other group which consists of baseline, 4 weeks' and 6 weeks' evaluations using the TMS, BRS, SSQOL and FMA-UE assessment instruments.

Control group:
1. Daytime activity:
1.1. First 30 minutes
Self-Range of motion and passive stretch exercises for the shoulder, elbow, wrist and thumb joints and muscles respectively according to Chart A. The rules of these exercises include keeping movements slow and controlled and to avoid rapid and jerky movements. The patient should hold each position for at least 5 seconds, or as indicated by the therapist. The patient must not force the movement. Exercises will cause a stretch but should not cause sharp pain. If exercises cause sharp pain, the patient must stop. This should be done 5 repetitions in each exercise activity and grading from large muscles and joints to small muscles and joints.
1.2. Second 30 minutes
Therapist uses proprioceptive and exteroceptive stimuli to elicit stretch reflexes such as quick stretch of agonist muscles 5 times and brushing of skin surface of the affected upper limb to facilitate movement responses 5 times. Patient can practice isometric muscle contractions of the shoulder and elbow on a stabilized surface like a small table for 5 repetitions each.
2. Night time treatment in the ward (30 minutes):
Each patient engages in the tasks written on the Activity Task Checklist which has a set of daily activities which require learning stabilization of objects using the affected upper limb. The patient is allowed to have rest breaks in between the activities when they feel tired. He or she can include other activities they want and incorporate the affected hand into the activities. The caregiver can write down the extra activities done by the patient if present so that they can be listed on the patient's prescription of daily task activities. The caregiver will be able to tick on the checklist when the activity has been done. As the patient does the activity, the caregiver can encourage bilateral use of hands and focus on stabilization and manipulation of objects using the affected hand.
Monday = Task 1-2
Tuesday = Task 3-4
Wednesday = Task 5-6
Thursday = Task 7-8
Friday = Task 1-2
Materials required for the tasks on the checklist:
Toothpaste and tooth brush
Books or newspapers
Clothes with zipper or buttons
Water bottle
Hair brush
Plate and food

Treatment group:
The treatment for the Treatment group will have same OT as control group, but with the Fourier M2 robotic rehabilitation machine and kinesiotherapy tape (KT). This will also take 1 hour during the day and 30 minutes during the night.
3. Daytime activity:
3.1. First 30 minutes:
Same as control group procedures.
3.2. Second 30 minutes
Each patient will have a KT placed on their upper limb areas such as the deltoid, biceps, middle and lower trapezius muscles. Each patient will sit on the Fourier M2 robotic machine and use the

handle assisted by therapist to pull/push to guide their upper limbs on the task given (harvesting fruits and vegetables displayed on the screen). The machine will have similar settings for patients in this group in the passive movement training mode. The machine will record factors such as the range of motion, moving trajectory and muscle strength.
4. Night time treatment in the ward (30 minutes):
Same as control group procedures.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measure as of 13/03/2019:
Upper limb function assessed by the therapist using the Fugl-Meyer for Upper Extremity (FMA-UE) scale while patient is sitting down at 1 week before treatment and 1 week after treatment

Previous primary outcome measure:
Motor threshold values assessed using Transcranial Magnetic Stimulation (TMS) at 1 week before treatment, 4 weeks after treatment initiation and 1 week after treatment completion

Key secondary outcome(s)
Current secondary outcome measures as of 21/05/2019:
1. Quality of life assessed using the Barthel Index (BI) scale answered by the patient or caregiver.
2. Stage of motor recovery assessed by the therapist using Brunnstrom's Recovery Stages (BRS) while observing the patient engage in small tasks suggested by Brunnstrom in the scale using the affected upper limb
All the evaluations will take place 1 week before treatment and 1 week after treatment completion.

Previous secondary outcome measures as of 13/03/2019:
1. Quality of life assessed using the Stroke Specific Quality of Life (SSQOL) scale answered by the patient or caregiver
2. Transcranial Magnetic Stimulator motor threshold (MT) presence or absence of stimulation of both upper limbs
3. Stage of motor recovery assessed by the therapist using Brunnstrom's Recovery Stages (BRS) while observing the patient engage in small tasks suggested by Brunnstrom in the scale using the affected upper limb
All the evaluations will take place 1 week before treatment and 1 week after treatment completion.

Previous secondary outcome measures:
1. Quality of life assessed using the Stroke Specific Quality of Life (SSQOL) scale answered by the patient or caregiver
2. Upper limb function assessed by the therapist using the Fugl-Meyer for Upper Extremity (FMA-UE) scale while patient is sitting down
3. Stage of motor recovery assessed by the therapist using Brunnstrom's Recovery Stages (BRS) while observing the patient engage in small tasks suggested by Brunnstrom in the scale using the affected upper limb
All the evaluations will take place 1 week before treatment, 4 weeks after treatment initiation and 1 week after treatment completion.

Completion date

30/11/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/05/2019:
1. Aged 45 to 75 years
2. Diagnosis of stroke or cerebrovascular accident identified by a neurologist or medical doctor using appropriate diagnostic tools such as MRI scan, CT scan and other relevant tools
3. First time stroke
4. Brunnstrom's stage 1 to 4 of the arm and hand
5. Registered at Xuzhou Rehabilitation Hospital
6. Participants should be co-operative and understand Chinese language

Previous inclusion criteria as of 13/03/2019:
1. Aged 45 to 75 years
2. Diagnosis of stroke or cerebrovascular accident identified by a neurologist or medical doctor using appropriate diagnostic tools such as MRI scan, CT scan and other relevant tools
3. First stroke that occurred less than 2 months previously
4. Brunnstrom's stage 1 and 2 of the arm and hand
5. Registered at Xuzhou Rehabilitation Hospital
6. Participants should be co-operative and understand Chinese language

Previous inclusion criteria as of 18/01/2019:
1. Aged 40 to 75 years
2. Diagnosis of stroke or cerebrovascular accident identified by a neurologist or medical doctor using appropriate diagnostic tools such as MRI scan, CT scan and other relevant tools
3. First stroke that occurred less than 2 months previously
4. Brunnstrom's stage 1 and 2 of the arm and hand
5. Registered at Xuzhou Rehabilitation Hospital
6. Participants should be co-operative and understand Chinese language

Previous inclusion criteria:
1. Aged 30 to 90 years
2. Diagnosis of stroke or cerebrovascular accident identified by a neurologist or medical doctor using appropriate diagnostic tools such as MRI scan, CT scan and other relevant tools
3. First stroke that occurred less than 3 months previously
4. Brunnstrom's stage 1 and 2 of the arm and hand
5. Registered at Xuzhou Rehabilitation Hospital
6. Participants should be co-operative and understand Chinese language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
Current exclusion criteria as of 21/05/2019:
1. Not co-operative
2. Do not speak Chinese language
3. Unstable patients
4. Patient of other hospitals in the same city
5. History of peripheral nerve injuries
6. History of neurosurgical treatments
7. Soft tissue tightness and musculoskeletal deformities not as a result of stroke
8. Brunnstrom's stages 5 and 6 of arm and hand
9. Comorbidities such as severe heart disease, liver disease, epilepsy, HIV infection, psychiatric problems, tuberculosis, infections or skin diseases
10. Patients who cannot speak or understand instructions

Previous exclusion criteria as of 18/01/2019:
1. Not co-operative
2. Do not speak Chinese language
3. Unstable patients
4. Patient of other hospitals in the same city
5. History of peripheral nerve injuries
6. History of neurosurgical treatments
7. Soft tissue tightness and musculoskeletal deformities not as a result of stroke
8. Brunnstrom's stages of 3, 4, 5 and 6 of arm and hand
9. Comorbidities such as severe heart disease, liver disease, epilepsy, HIV infection, psychiatric problems, tuberculosis, infections or skin diseases
10. Patients who cannot speak or understand instructions

Previous exclusion criteria:
1. Not co-operative
2. Do not speak Chinese language
3. Unstable patients
4. Patient of other hospitals in the same city
5. History of peripheral nerve injuries
6. History of neurosurgical treatments
7. Soft tissue tightness and musculoskeletal deformities not as a result of stroke
8. Brunnstrom's stages of 3, 4, 5 and 6 of arm and hand
9. Comorbidities such as severe heart disease, liver disease, epilepsy, HIV infection, psychiatric problems, tuberculosis, infections or skin diseases

Date of first enrolment
20/12/2018

Date of final enrolment

30/09/2019

Locations

Countries of recruitment
China

Study participating centre
Xuzhou Rehabilitation Hospital
10 Kui Zhong Xiang
Jianguo East Road
Yunlong District
Xuzhou
China
221006

Sponsor information

Organisation
Xuzhou Rehabilitation Hospital

Funder(s)

Funder type
Government

Funder Name
Jiangsu Youth Medical Talent Fund (Jiangsu Provincial Medical Youth Talent QNRC2016376)

Funder Name
Xuzhou City Medical Young Reserve Talents Project Grant (Xuzhou Medical Young Talents Project 2016015)

Results and Publications

Individual participant data (IPD) sharing plan
The data sets generated during and/or analyzed during the current study will be available and included in the subsequent results publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	22/05/2020	Yes	No
Participant information sheet		26/11/2018	28/11/2018	No	Yes