APPLYING SPORT AND EXERCISE SCIENCE TO A NATIONAL INSTITUTE FOR HEALTH RESEARCH STUDY INVOLVING NHS PATIENTS:

GAINING RESEARCH COUNCIL FUNDING TO DEVELOP A PERIOPERATIVE ISOMETRIC-RESISTANCE EXERCISE INTERVENTION FOR PATIENTS UNDERGOING ELECTIVE ABDOMINAL CANCER SURGERY.

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What we’re going to cover:

• A review of a feasibility study
• Recap on how we got there; achieving research council (NIHR) funding
• What’s required in order to develop a streamlined and fundable bid
DEVELOPMENT OF COMPLEX INTERVENTIONS: MRC GUIDELINES

**Feasibility and piloting**
- Testing procedures
- Estimating recruitment and retention
- Determining sample size

**Development**
- Identifying the evidence base
- Identifying or developing theory
- Modelling process and outcomes

**Evaluation**
- Assessing effectiveness
- Understanding change process
- Assessing cost effectiveness

**Implementation**
- Dissemination
- Surveillance and monitoring
- Long term follow-up
OVERVIEW OF THE STUDY:

NATIONAL INSTITUTE FOR HEALTH GRANT-FUNDED PROJECT (RESEARCH FOR PATIENT BENEFIT)

A FEASIBILITY STUDY

Towards a multi-centre randomised controlled trial
THE RESEARCH PROBLEM:

Up to 80% loss of physical function
SUCCESSFUL FUNDING TEAM

- **Sponsor**: Maidstone & Tunbridge Wells NHS Trust, Department of Surgery
- **Mr Haythem Ali** (Chief Investigator).
- **Professor Ian Swaine**, University of Greenwich (Project Lead)
- **Ms Julie Knowles** (Maidstone & Tunbridge Wells R&D).
- **Dr Ferhana Hashem** (University of Kent Centre for Health Services Research).
- **Dr David Stephensen** (East Kent Hospitals University Foundation Trust).
- **Dr Kevin Corbett**, Middlesex University.
- **Lee Tomlinson** (Specialist Research Nurse, at the time).
ALSO INCLUDED IN THE PROJECT TEAM:-,

- David Lowery, Trial Methods Research Fellow, University of Kent
- Charitini Stavropoulou, Senior Lecturer in Health Management, City University
- Amanda Bates, Patient and Public Involvement, Public Engagement Officer, University of Kent
- Nobby Hobbs, Patient and Public Involvement Representative
- Hazel Westwood, Patient and Public Involvement Representative
- Malcolm Hopkins, Patient and Public Involvement Representative
- Mossie Francis, Patient Research Ambassador, Maidstone & Tunbridge Wells NHS Trust
IAN SWAIN:  

10+ YEARS OF RESEARCH EXPLORING THE PHYSIOLOGICAL EFFECTS OF EXERCISE.  

The work of 6 PhD students!
KEVIN CORBETT:

10+ YEARS OF MIXED METHODS HEALTH RESEARCH EXPLORING USER INVOLVEMENT AND PATIENT INTERVENTIONS
FUNDING PROCESS

- Took 3 years (3 application cycles).
- Started with Haythem Ali approaching Ian Swaine with idea, via CLRN (following Kevin undertaking a public health fellowship suggested Ian approach Kent CLRN).
- Ian discusses ideas with CLRN and then the Kent Research Design Service (University of Kent)
- Write a ‘Research Protocol’ (with Haythem and Lee Tomlinson).
FUNDING PROCESS

- PPI was simply a series of email exchanges with patients.
- First application submitted 6 months later (NIHR Programme Development Grants).
- (In spite of concerns of Finance Officer and Ferhana).
FUNDING PROCESS

- Feedback from the first application.
- Suggested RfPB instead.
FUNDING PROCESS

- Re-submission to RfPB this time.
- Feedback not wholly positive again.
- 3rd Submission in September 2013
- Outcome March 2014
Q. BUT HOW CAN THIS WORK BE APPLIED, WITHIN WIDER SOCIETY, TO HAVE AN IMPACT?

Answer: NHS work with patients
RESEARCH FOR PATIENT BENEFIT (RFPB) GRANT AWARDED IN 2015

HIGH IMPACT RESEARCH?
RESEARCH FOR PATIENT BENEFIT

Must involve patients at every stage. The development of new interventions must partly be governed by them.
RESISTANCE EXERCISE

Muscle-strengthening.
OUTCOME MEASURES?

Physical function (physical performance test battery)
1. Balance tests

- Side-by-side Stand
  - For 10 sec
  - 10 s (± 1 s) < 10 sec (0 pt)
  - Go to 2. Gait Speed Test

- Semi-Tandem Stand
  - For 10 sec
  - 10 s (± 1 s) < 30 sec (0 pt)
  - Go to 3. Chair Stand Test

- Tandem stand
  - For 10 sec
  - 10 s (± 2 s) < 30 s (± 1 s) < 90 s (± 1 s) < 15 s (± 0 s)

2. Gait Speed Test

- Measures the time required to walk 4 meters at a normal pace (use best of 2 times)
- Points: _____ pt

3. Chair Stand Test

- Pre-test
  - Participants must have arms extended when seated and try to stand upright from a chair
- 5 repeats
  - Measures the time required to perform five rises from a chair to an upright position as fast as possible without the use of the arms

- Total points: _____ pt

Results:
- SPPB 0-6: Poor performance
- SPPB 7-9: Intermediate performance
- SPPB 10-12: High Performance
OUTCOME MEASURES – FEASIBILITY?

Willingness of patients to be recruited?
Willingness to be randomised?
Completion of programme?
Adverse incidents?
Is it feasible to assess physical performance test battery?
A TWO-PHASE STUDY

1. Development of intervention (involving patients - qualitative: focus groups & Delphi method).
2. Small-scale feasibility trial (quantitative outcomes measurement & qualitative).
CURRENTLY IN PHASE 1
DEVELOPMENT OF INTERVENTION?

1. The research team outlines general exercise programme structure, based on a systematic literature review.
2. A multitude of exercises were presented to four patient focus groups to solicit their views.
3. Favoured exercises are then subjected to a DELPHI process.
DELPHI METHOD

1. Named after the oracle in Delphi, ancient Greece, who was consulted for “expertise” on making life choices.
2. A structured communication technique or method, originally developed as a systematic, interactive forecasting method which relies on a panel of experts who answer questions in rounds.
3. Five expert sub-groups (patients, surgeons, nurses, physiotherapists and exercise scientists).
4. Elicits opinions about suitability of INTERVENTION and OUTCOMES are surveyed (online using Qualtrics software).
5. Try to achieve consensus by giving feedback after each round to all groups about their choices.
6. Responses are analysed and a consensus is sought.
THE EXERCISE PROGRAMME

Four stages:
1. pre-operative,
2. early post-operative (0-2 weeks),
3. mid-term post-operative (2-6c weeks) and
4. longer-term post-operative (6-12 weeks).

10 Exercises: utilising 5 body areas.
DELPHI METHOD

TWO PARALLEL SURVEYS:
1. INTERVENTION
2. OUTCOMES
Exercise 1 – Abdominal Muscles 1:

Option A:
Lying on your back with your knees bent.
Bend the chin towards your chest and lift your head. Lower your head while keeping your chin as close as possible to the chest.
Repeat X times.

Option B:
Lying on your back with knees bent and arms by your side.
Tighten your stomach muscles and press the small of your back against the floor letting your bottom rise.
Hold for X seconds, then relax. Repeat X times.

Option C:
Lying on your back with knees bent and feet on the floor.
Lift your pelvis and lower back (gradually vertebra by vertebra) off the floor. Hold the position. Lower down slowly returning to starting position.
Repeat X times.
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Repeat X times.

Exercise 2 – Arms and Shoulders 1:

Option A:
Stand or sit. Hold an exercise band with both arms straight in front of you.
Pull the band with both arms and tighten your shoulder blade muscles. Do not lift your shoulders. Repeat X times.

Option B:
Sit. Support your forearm on your thigh. Place an exercise band under your feet and hold the band with your palm up.
Bend your wrist up.
Repeat X times. Then, repeat with other arm.

Option C:
Lie on your back with an exercise band looped at each end and the loops around the hands.
Start with the arms pointing towards the ceiling and pull the arms out to the side keeping the arms straight. Your elbows should be in a direct line with your shoulders, forming a “T” shape as shown in the picture. Use the colour exercise band. Hold for X seconds.
Exercise 3 – Trunk and Legs 1:

Option A:
Sit with your hands on your waist.
Stand up by tightening your buttock muscles and then slowly sit down.
Repeat X times.

Option B:
Sit on a chair.
Pick up and put down a ball with your feet.
Repeat X times.

Option C:
Sit on a chair. Put a rubber exercise band around your knees.
Spread knees apart. Slowly bring knees back together.
Repeat X times.

Exercise 4 – Hand and Arm 1:

Option A:
Lying on your back. Elbow bent at a right angle close to your body. Hold on to your wrist with the other hand.
Try to move your hand inwards while resisting any movement with your other hand.
Hold for X seconds.
Repeat X times.

Option B:
Stand. Grasp the wrist of the arm you want to exercise.
Bend your elbow and assist the movement with your other hand. Straighten your elbow.
Repeat X times.

Option C:
Stand or sit. Hold your upper arm close to your body with your elbow at a right angle.
Try to move your hand outward, resisting the movement with the other hand. There should be no movement.
Hold for X seconds. Repeat X times.
Exercise 5 – Foot and Lower Leg 1:

Option A:
Sit on the floor or on a chair. Put a rubber exercise band around your foot.
Point your toes towards the floor. Slowly return to starting position.
Repeat X times.

Option B:
Lying on your back with a cushion under your head. Put a band under the ball of your foot and hold on to the band with both hands.
Bend and straighten your ankle slowly.
Repeat X times.

Option C:
Sit on a chair or on the floor. Put one foot on top of the other foot.
Try to lift the foot that is under while preventing any movement with the foot that is on top.
Hold for X secs. Repeat X times.

Exercise 6 – Abdominal Muscles 2:

(No Options)

Exercise 7 – Arms and Shoulders 2:

(No Options)

Exercise 8 – Trunk and Legs 2:

(No Options)
Interactional Expertise

- 'Interactional expertise' offers a theoretical framework for interdisciplinary team working.
- Instead of a new language emerging, some members of the group learn the language of others and shift back and forth between the different worlds represented by team members.
- This is more akin to translation between cultures rather than the creation of a new, shared, culture.

Contributory Expertise

- The expertise needed to contribute fully to all aspects of a domain of practice e.g. sports/exercise science, physiotherapy, surgery, health economics etc., etc.
- What is normally thought of as an 'expertise'
- The practical expertise that enables one to contribute to a domain of practice.
- To acquire contributory expertise one must work within the expert domain.

How does this team work together?


FUTURE PHASE 2
CONCLUSIONS

Successful development of an exercise programme that has involved patients and subject (domain specialists).
Follows MRC guidelines on development of complex interventions.
Originates & tests the feasibility of an exercise intervention of potential utility for post-operative abdominal cancer patients.
KEY MESSAGES

- Gaining research council funding relies on successful networking **over time which identifies, and capitalises on, different forms of expertise**

- The research team must effectively draw upon different types of requisite expertise (‘epistemologies’) from Patients through to domain specialists like Surgeons, Exercise Scientists, Physiotherapists, Methodologists, Health Economists etc.

- Team members need to be:
  - easy-going.
  - mutually respectful.
  - mutually responsive.
  - enjoyable company!