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IODA pilot study

Feasibility of conducting a pragmatic, randomized trial that compares Immediate versus Optional Delayed surgical repair for treatment of acute anterior cruciate ligament injury

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Why this feasibility study?

- General belief that surgery is necessary after ACL injury

Only 2 prior RCTs

→ no effect in Belgium

→ 50% still need surgery

- Current practice is eminence-based
- Patients have strong preference for particular treatment

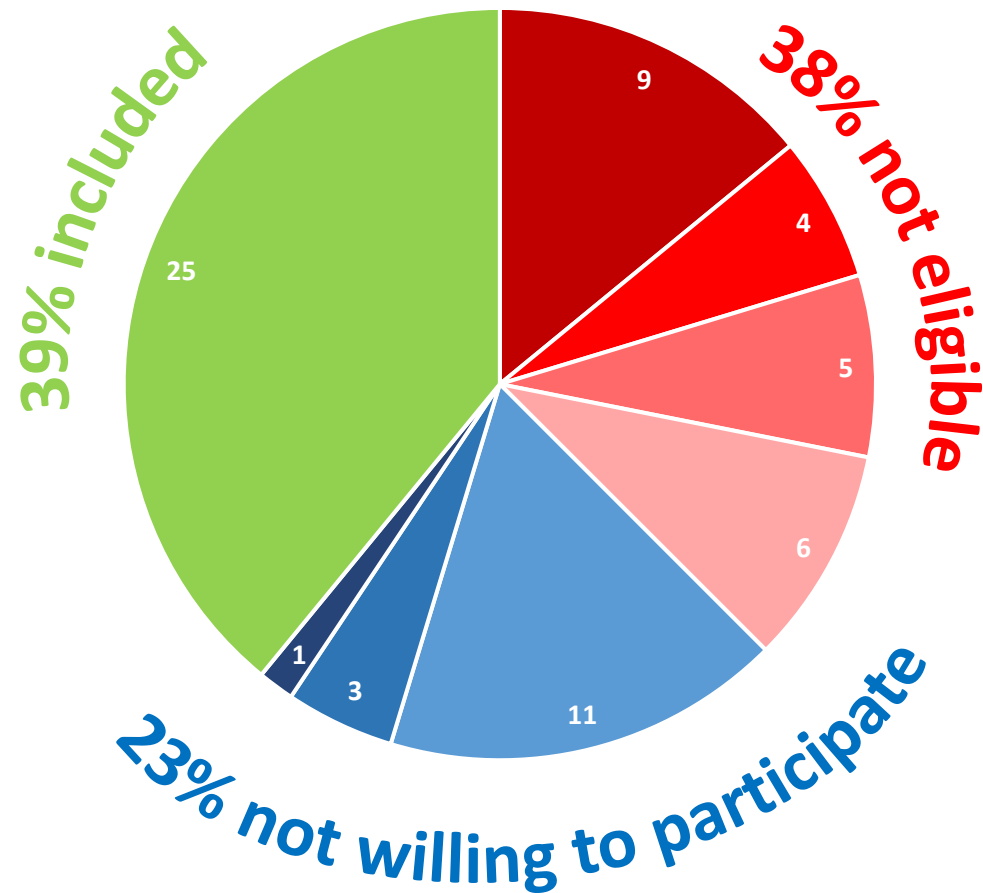
Design

RCT

- Similar protocol as full study
- Shorter follow-up
- Only 2 hospitals

Primary outcome: recruitment rate

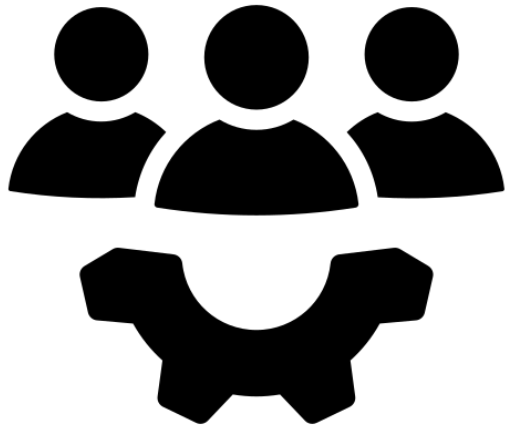
Results



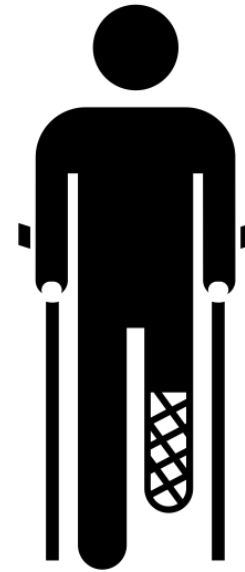
- no acute ACL injury (n=9)
- age (n=4)
- previous ACL injury (n=5)
- indication for surgery (n=6)
- preference surgery (n=11)
- preference conservative treatment (n=3)
- not interested (n=1)
- included (n=25)

Recruitment challenges

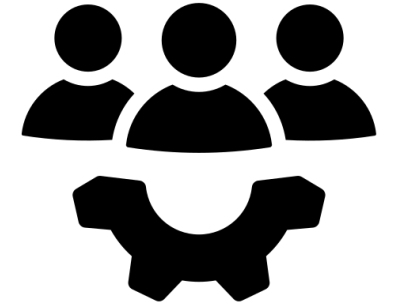
Team



Patient



Recruitment challenges – Team related



Close collaboration
& efficient referral



Beliefs of team



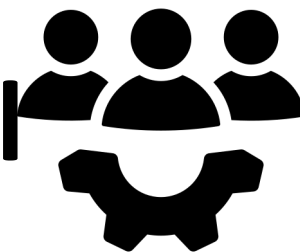
‘Phased’ study information



Patient care remains priority



Close collaboration & efficient referral



Emergency care

Orthopedics

Physical medicine

Sports clubs, physiotherapists

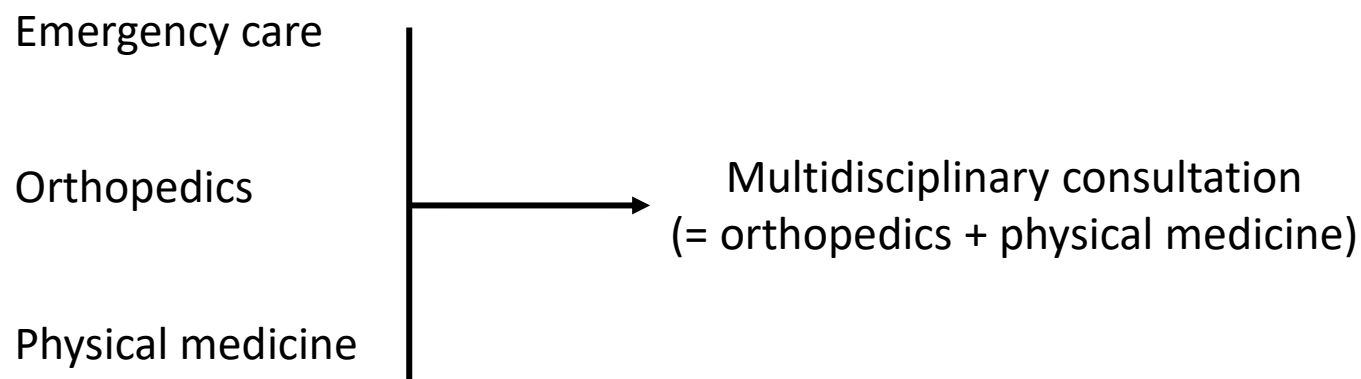
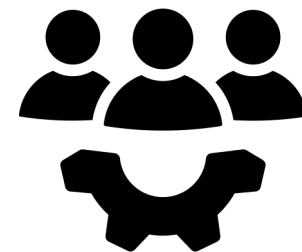
...

Close
collaboration
Efficient referral

Multidisciplinary consultation
(= orthopedics + physical medicine)



Providing phased study information



Unbiased explanation of
the 2 treatment options



1) 2 treatment options
2) 3th option: study



Interested?
Full explanation by study
assistant



Beliefs of the team



- Distancing from experiences and thoughts
- “I know which patients need surgery”
- Barrier for surgeons to participate in the trial

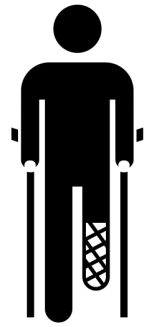


Patient care remains priority!

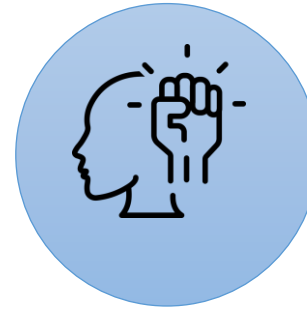


- “No matter what, we will continue to take good care of you”
- No ‘selling’

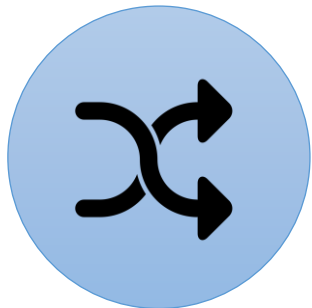
Recruitment challenges – patient related



Patient-tailored explanation



Patient's autonomy



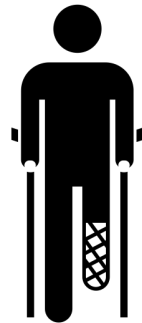
Explain randomization



Advantages



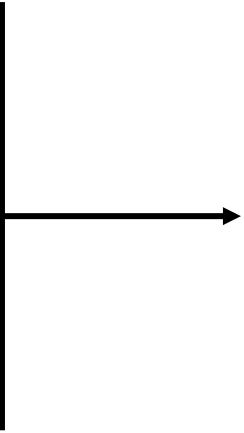
Patient-tailored explanation



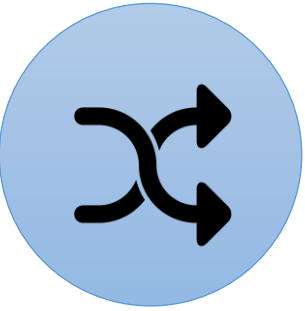
Preference

Neutral

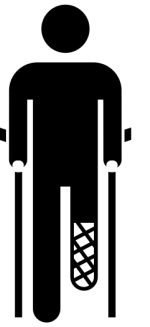
Uncertain



Provide neutral, comprehensive information
without selling the study



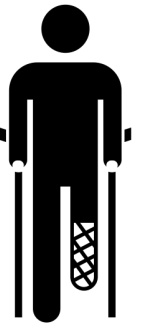
Explain randomization



- Computer assigns treatment
→ concealed and determined solely by the computer
- No logic order in the allocation = 'RANDOM'



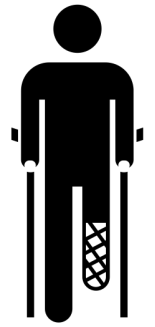
Patient's autonomy



- Patients:
 - maintain autonomy regarding their participation in the study
 - have the right to withdraw at any time



Advantages for all



Patients

Additional testing, enhanced follow-up, more time with medical staff

Society

Individualized treatment approach → less unnecessary surgery

Research

Our field of interest → quality of our study depends on willingness to participate in a RCT

Good luck with your trial!

... and feel free to share your tips with us

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