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Hoe schrijf ik een onderzoeksprotocol?

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Disclosure

Disclosure Belangen Spreker

Geen (potentiële) belangenverstengeling	
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Functional treatment versus plaster for simple elbow dislocations (FuncSiE): a randomized trial

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WMO..... wat is dat?

- Wet Medisch-wetenschappelijk Onderzoek met mensen
- Onderzoek valt onder de WMO als het aan de volgende twee voorwaarden voldoet:
 - Er is sprake van medisch wetenschappelijk onderzoek én
 - Personen worden aan handelingen onderworpen of hen worden gedragsregels opgelegd

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SPIRIT (http://www.spirit-statement.org)

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

The SPIRIT Statement

The SPIRIT 2013 Statement provides recommendations for a minimum set of scientific, ethical, and administrative elements that should be addressed in a clinical trial protocol. The Statement also details the scope and systematic development methods of the SPIRIT guidance.

The recommendations are outlined in a 33-item checklist and figure. Important details for each checklist item can be found in the Explanation & Elaboration paper, or by lowering the menu on the left. The minimum list of items is by no means exhaustive; particular types of trials warrant additional protocol elements.

SPIRIT Checklist

Publications & Downloads

Template onderzoeksprotocol (www.ccmo.nl)

ccmo Centrale Commissie Mensgebonden Onderzoek

Onderzoekers METC's Proefpersonen Bibliotheek CCMO

- Help mij op weg!
- Medisch-wetenschappelijk onderzoek en de WMO
- Presanre indering bij de toelatingcommissie
- Geneesmiddelenonderzoek & extra veiligheidsmonitoring
- Standaardonderzoeksonderzoek
- Tijdschrift voor het onderzoek
- Soorten onderzoek
- Huidgevoel

Een pdf met een overzicht van en toelichting op het gehele standaardonderzoeksonderzoek voor u hier

Doelen

- **Primair doel:** Altijd!
Uitkomst, interventie, populatie, aandoening
- Noem **secundaire doelen** indien van toepassing
- Toetsbare hypothesen

Doelen FuncSiE trial

- **Primair:** Vergelijken van de Quick-DASH score (Disabilities of the Arm, Shoulder, and Hand; maat voor functie en pijn) na vroeg mobilisatie versus gipsimmobilisatie bij volwassenen (18+) na een simpele elleboogluxatie
- Hypothese: DASH (mobilisatie) < DASH (gips)
- Secundair:

Inhoud onderzoeksprotocol

- Titelpagina
- Samenvatting
- Achtergrond en doelen
- Studiedesign
- Data-analyse
- Dataopslag
- Ethiek
- Veiligheid
- Referenties en bijlagen

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Studiedesign

- Design
- Onderzoekspopulatie: inclusie- en exclusiecriteria
- Steekproef (NB: mortaliteit, drop out!)
- (Na-)behandeling: standaardisatie?
- Hoe wordt bias voorkomen? Blinding?
- Follow-up: frequentie en duur
- Uitkomstmaten: welke en hoe te bepalen
- Overige data

Studiedesign

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Design, in-/exclusiecriteria FuncSiE trial

- **Design:** multicenter RCT, parallele groepen, 1:1 randomisatie
- **Inclusiecriteria:**
 - Leeftijd 18 jaar of ouder
 - Eenvoudige elleboogluxatie, die gesloten gereponeerd is
 - Informed consent door de patiënt
- **Exclusiecriteria:**
 - Additioneel letsel aangedane arm indien dit revalidatie beïnvloedt
 - Complexe, recidief of open luxatie
 - Eerdere operaties of verstoorde elleboogfunctie
 - Reumatoïde artritis
 - Te verwachten problemen met FU (NL taal, cognitie, therapietrouw)

Studiedesign

- Design
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- Overige data



Steekproef FuncSiE trial

- Literatuur: *Quick*-DASH score 12.5 ± 15 (gips) ¹
- Verwacht: 5.0 ± 7.5 (mobiliseren)
- Tweezijdig testen, $\alpha 0.05$, $\beta 0.2$
- Nodig: 41 patiënten per groep
- Dropout rate 20%
- **Totaal: 50 patiënten per groep**

¹ Maripuri et al. Injury 2007; 38:1254-1258



Interventie en nabehandeling FuncSiE trial

- **Interventie:**
 - Gipsimmobilisatie: 3 weken, lokaal protocol gipswissel
 - Vroeg mobiliseren: 1-7 dagen Tubigrip/drukverband
Na 1 dag o.g.v. pijn mobiliseren
- **Nabehandeling:** Richtlijnen fysiotherapie
- **Blinding:** X-evaluatie, standaard meetprotocol, statisticus
- **Follow-up:** 1, 3 en 6 weken, 3, 6 en 12 maanden (+ window)



Studiedesign

- Design
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- Overige data



Uitkomstmaten FuncSiE trial

- **Primair:** *Quick*-DASH score
- **Secundair:**
 - **Klinisch:** ROM, AE, secundaire interventies
Degeneratieve veranderingen, ossificaties
 - **Patiënt:** Pijn: VAS, NRS
Functie: MEPI, OES
QoL: SF-36, EQ-5D
 - **Maatschappij:** Zorggebruik: Kosten-effectiviteit



Overige data FuncSiE trial

- **Intrinsieke variabelen (baseline data):**
 - Leeftijd / geslacht / BMI / ASA graad / alcohol & roken / comorbiditeit / medicatie / dominante zijde
- **Letsel-gerelateerde variabelen:**
 - Aangedane zijde / traumamechanisme / letselclassificatie
- **Interventie-gerelateerde variabelen:**
 - Behandel delay / dagen sling / tijd tot fysio / aantal fysio



Inhoud onderzoeksprotocol

- Titelpagina
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Data-analyse

- Statistisch programma (SPSS, SAS, STATA, R,)
- Datapresentatie: gem. (SD, 95% BI), mediaan (Q₁-Q₃), N (%)
- Analyse: descriptief, uni/multivariaat
- Intention to treat / per protocol
- Interim analyse
- Geplande subgroepanalyse
- Stopping rules



Dataopslag

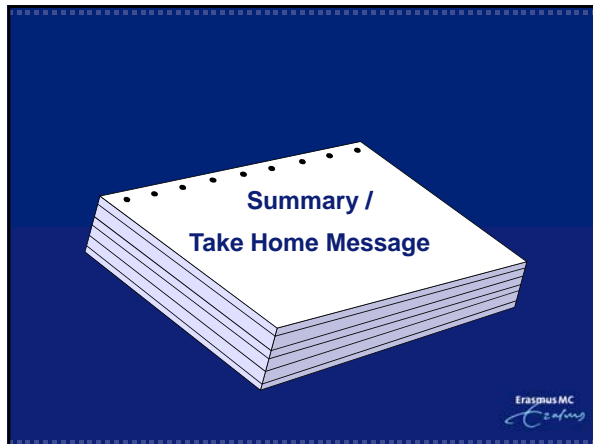
- Type database: OpenClinica
- Wie heeft toegang tot data?
- Anoniem / codering
- Publicatieafspraken



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3. STUDY DESIGN	3
4. STUDY POPULATION	4
4.1 Population base	4
4.2 Inclusion criteria	4



Hoe maak je (voor het eerst) een protocol?

- Vraag een ervaren team om hulp !
- Gebruik online bronnen:
 - Website CCMO, METC, researchbureau
 - BMC journals



de Haan et al. BMC Musculoskeletal Disorders 2016, 15:263
http://www.biomedcentral.com/10.1186/s12913-016-1128-8

BMC Musculoskeletal Disorders Open Access

STUDY PROTOCOL

Functional treatment versus plaster for simple elbow dislocations (FuncSiE): a randomized trial

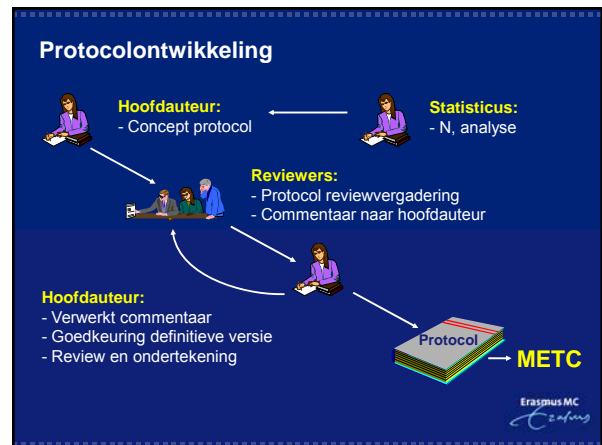
Jeroen de Haan¹, Dennis den Hartog², Wim E. Tulvinger³, Gips H. Iordens⁴, Roelof S. Breeckerveel⁵, Maarten WGA Broekmans⁶, Milou MM Bruggink⁷, Mark R. De Vries⁸, Soudewijn J. Driess⁹, Dennis Eggenhuis¹⁰, Robert Haverlaag¹¹, Sven AG Moysaerts¹², Jan-Willem R. Mulder¹³, Kees J. Ponsioen¹⁴, W. Herbert Roerdink¹⁵, Gerrit R. Roukema¹⁶, Inger B. Schipper¹⁷, Michel A. Schouten¹⁸, Jan Bernard Sintese¹⁹, Serral Soro²⁰, Johan G. Van den Brand²¹, Hub GWM Van den Meulen²², Tom TH Van Thiel²³, Arie B. Van Vugt²⁴, Egbert JMM Veredoren²⁵, Jos PAM Vroomen²⁶, Marco Waalboer²⁷, W. Jaap Willem²⁸, Suzanne Polinder²⁹, Peter Patka³⁰, Esther MM van Lieshout³¹, Niels W. Schep³²

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Wie levert input voor het protocol?


- Hoofdauteur
- Hoofdonderzoeker
- Mede-onderzoekers / lokale onderzoekers
- Onderzoeksassistent
- Statisticus
- Datamanager
- Database bouwer
- Monitor

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Een goed protocol...

- Beantwoordt de studievraag met inachtneming van wettelijke verplichtingen
- Leidt tot efficiënt studieverloop, met complete dataverzameling, processing, analyse en rapportage
- **Bevat de inleiding en methode van je publicatie (!)**



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Websites

- <http://www.ccmo.nl>
- <http://www.spirit-statement.org>
- <https://www.vumc.nl/afdelingen/METC/wmo-ordeel/voorb/onderzoeksvoorstel/>
- <http://www.erasmusmc.nl/commissies-cs/metc-cs/365743/METCleidraadstatistiekprotocollen>
- <http://clincalc.com/stats/samplesize.aspx>
- https://wikistatistiek.amc.nl/index.php/KEUZE_TOETS

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