



**EFFECTS** Efficacy of Fluoxetine – a randomisEd Controlled Trial in Stroke

---

# Prövvarmöte EFFECTS

Stockholm 25 januari 2019



Erik Lundström  
Associate professor at KI  
Adj senior lecturer at  
Uppsala University  
Chief-investigator EFFECTS



Eva Isaksson  
RN/ PhD student at KI  
Trial Manager EFFECTS



Nina Greilert  
RN  
TMA EFFECTS

“

## WHY WE MUST FINISH EFFECTS

1. FOCUS AND EFFECTS ARE SIMILAR BUT NOT IDENTICAL
2. EFFECTS HAS SOME UNIQUE FLAVOURS
3. NO SIGNS OF SEVERE SIDE EFFECTS IN FOCUS
4. PROBLEMS OF STOPPING STUDIES EARLY

”

## FOCUS VS EFFECTS

<b>FOCUS</b>	<b>EFFECTS</b>
More severe stroke (median NIHSS 6)	Median NIHSS 3
Less organised stroke rehab (1)	More organised rehabilitation Maybe more own training (?) ↑
Less adherence (67%)	More adherence (90?) <i>preliminary data!</i>

(1) Use of time by stroke patients: a comparison of four European rehabilitation centers.  
Stroke. 2005 Sep;36(9):1977-83. De Wit et al

“

## UNIQUE FLAVOURS OF EFFECTS

1. DATA ON PHYSICAL TRAINING
2. MEASURE OF COGNITION (MOCA)
3. MEASURE MADRS
4. POSSIBILITY TO LONG TIME F/U LINKED TO HIGH-QUALITY REGISTRIES IN SWEDEN

”

“

## NO SIGNS OF SEVERE SIDE EFFECTS IN FOCUS

- BLEEDINGS - NO
- FRACTURES – IS IT REAL?
- SEIZURES AND FLUOXETINE (?)
- INTERACTION BETWEEN METOPROLOL AND FLUOXETINE  
IN PAT WITH CARDIAC HEART FAILURE (?)

”



# THE HARM TO STOP STUDIE PREMATURE

- EFFECTS IS POWERED FOR 1,500
  - WHAT IF WE FIND A BORDERLINE SIGNIFICANCE

## Analysis

### Problems of stopping trials early

*BMJ* 2012 ; 344 doi: <https://doi.org/10.1136/bmj.e3863> (Published 15 June 2012)

Cite this as: *BMJ* 2012;344:e3863



“

EFFECTS WILL IMPROVE THE EXTERNAL VALIDITY AND PRECISION OF  
THE ESTIMATES OF THE EFFICACY AND SAFETY OF FLUOXETINE IN  
ISCHAEMIC AND HAEMORRHAGIC STROKE

”

“

1 375

”

DECEMBER = 25

JAN = 29 (AND STILL COUNTING)

FEB

MARS

APRIL 1 500



We must carry on











