



# The Phy-Psy Trial



A cluster randomised, parallel-group, 5-year trial of coordinated, co-produced care to reduce the excess mortality of patients with severe mental illness by improving the treatment of their comorbid physical conditions

Niels de Fine Olivarius

Center for Research  
and Education  
in General Practice



Psykiatri

# Structured **personal** care

## Structure and follow-up

- 3-monthly examinations
- Yearly examinations

## Patient involvement

- **Personal treatment goals**
- Patient folders

## Written material for GPs

- Clinical guidelines
- Folders

## Seminars and feed-back

- Yearly ½-day seminars for GPs
- Yearly reports on course of treatment for individual patients

# Effect for patients **with** and **without** severe mental illness (SMI)

## Relative risk reduction for intervention, %

...during 19 years after diabetes diagnosis

	<b>SMI</b>	<b>No SMI</b>
<b>Any diabetes-related outcome</b>	<b>53</b>	<b>17</b>
<b>Diabetes-related death</b>	<b>43</b>	-1
<b>All-cause mortality</b>	<b>37</b>	4
<b>Myocardial infarction</b>	<b>52</b>	16
Stroke	37	7

# Conclusion: SMI

The results suggest that  
patients with SMI are more - not less -  
susceptible to intervention  
than patients without SMI...

...because of their a priori high risk of getting an outcome!

It is “logik for høns” = plain as a pikestaff ,  
....that this risk is easier to reduce than for low risk patients



# The Phy-Psy Trial



A cluster **randomised**, parallel-group, 5-year **trial** of **coordinated, co-produced care** to reduce the **excess mortality** of patients with **severe mental illness** by improving the **treatment of their comorbid physical conditions**

Niels de Fine Olivarius

Center for Research  
and Education  
in General Practice



Psykiatri

# Our ambition

The Phy-Psy Trial will  
reduce the all-cause mortality  
of people with severe mental illness by  
33%



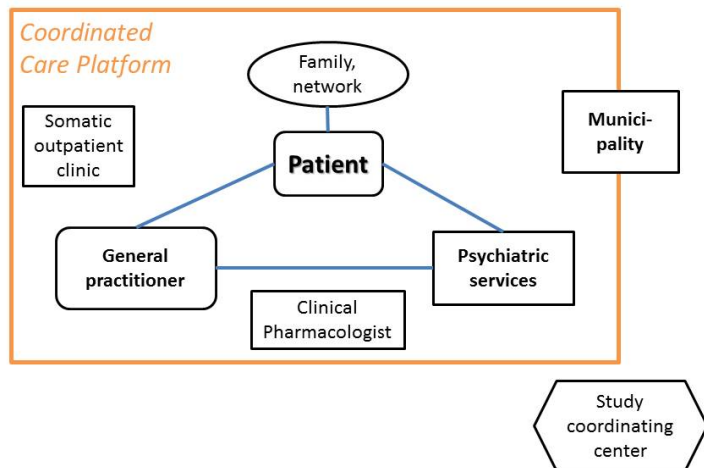
# The why and how – in brief

	<b>Present situation</b>	<b>The Phy-Psy Trial</b>
<b>Patients</b>	<ul style="list-style-type: none"> <li>Patients with severe mental illnesses</li> </ul>	<ul style="list-style-type: none"> <li>Unselected sample of serious cases</li> </ul>
<b>Health care services / Caregivers</b>	<ul style="list-style-type: none"> <li>General practice, hospital psychiatry and municipalities with insufficient coordination</li> </ul>	<ul style="list-style-type: none"> <li>Coordinated care plan with individualized goals involving all existing caregivers</li> </ul>
<b>Treatment</b>	<ul style="list-style-type: none"> <li>Physical disease: Under-diagnosis/undertreatment</li> <li>Psychiatric disease: Polypharmacy</li> </ul>	<ul style="list-style-type: none"> <li>Improved detection and pharmacological treatment</li> </ul>
<b>Outcome</b>	<ul style="list-style-type: none"> <li>Overmortality</li> </ul>	<ul style="list-style-type: none"> <li>Reduced overmortality</li> </ul>



# The coordinated care platform

## Coordination - Continuity - Commitment



- Commitment of all stakeholders through efficient **communication (also with ICT)** and **well-defined roles** for all stakeholders
- A pivotal role for **general practice**: continuity, coordination, detection, treatment
- Patient-centred treatment, **individualised** goal-setting **(also with PHT)**
- A **structured** treatment course



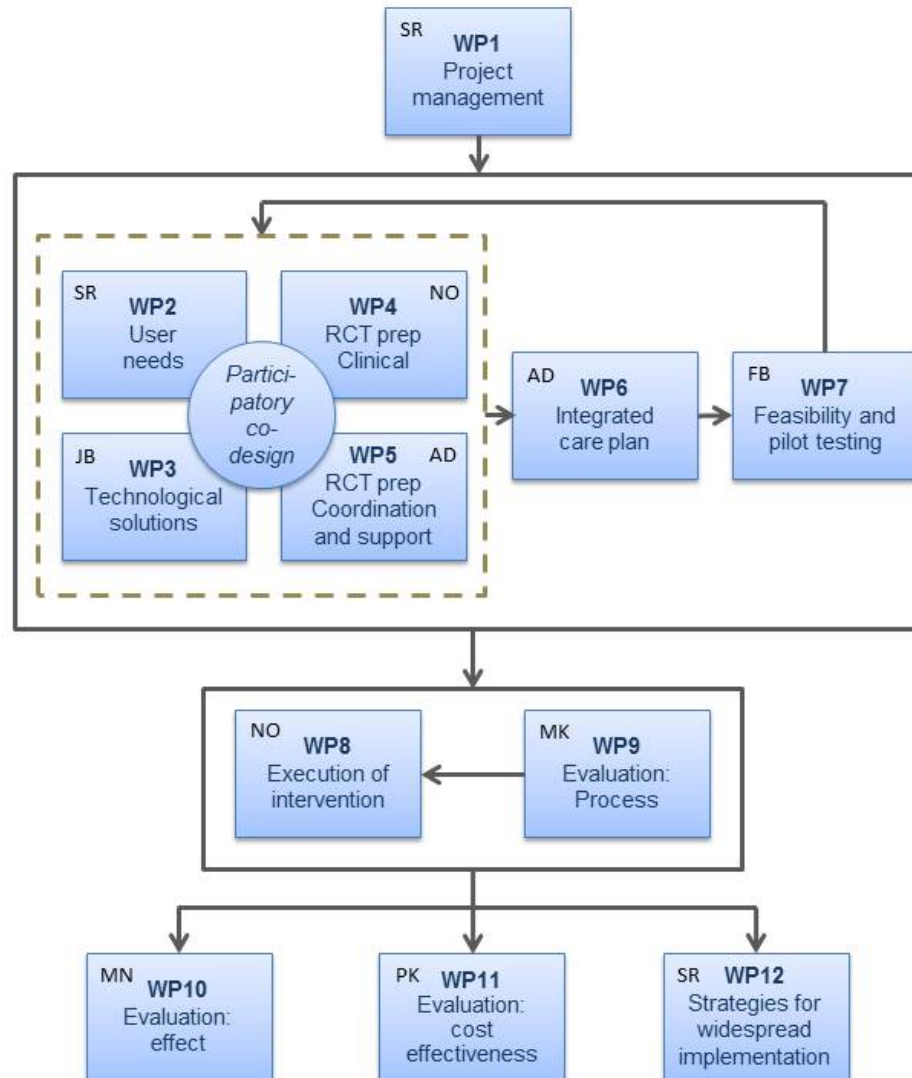


# Quantitative and qualitative research methods are integrated

- Cluster randomised, parallel-group, 5-year **adaptive** trial
- Aim: to demonstrate the real-world effectiveness of a **complex intervention** in an unselected sample of patients with SMI
- Combining clinical, social, and technological science, theory and qualitative and quantitative research methods in a **co-design process**



# Workflow



Preparation  
2 y.

Execution  
5 y.

Evaluation  
2 y.

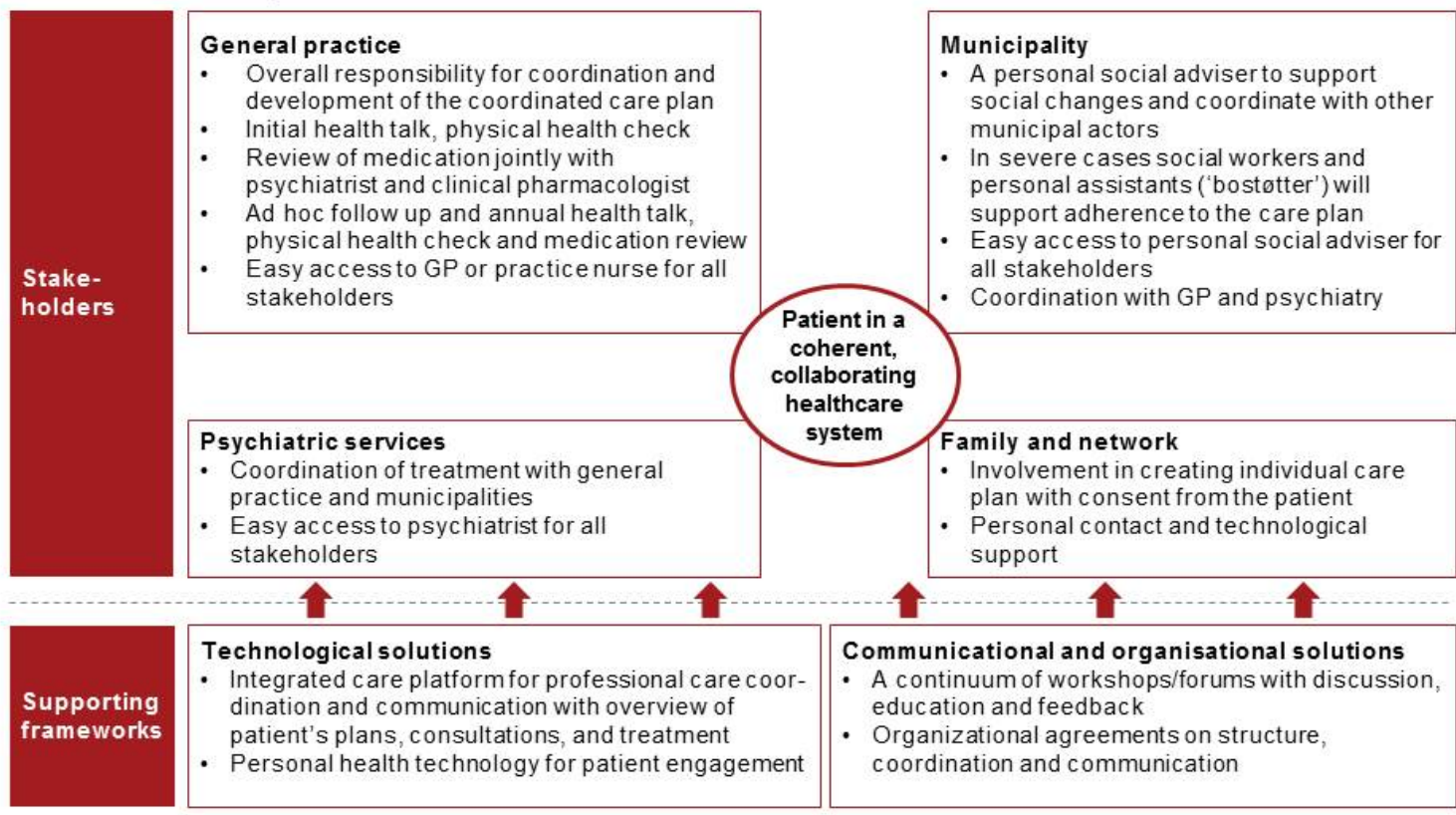
10



# The intervention

- Improving the **detection and pharmacological treatment of physical diseases** - alongside viable lifestyle changes
- **Individual care plans** to follow patients in efficient cross-sectorial collaboration
- Structured patient care with **individualised goal-setting** to ensure patient involvement
- **Recognised methods and tools** selected in the co-design process
- **Harmful effects of psychoactive drugs and drug interactions** minimised

## The coordinated care plan



# The intervention

- Improving the **detection and pharmacological treatment of physical diseases** - alongside viable lifestyle changes
- **Individual care plans** to follow patients in efficient cross-sectorial collaboration
- Structured patient care with **individualised goal-setting** to ensure patient involvement
- **Recognised methods and tools** selected in the co-design process
- Harmful **effects of psychoactive drugs and drug interactions** minimised

The c

## Technological solutions

- Integrated care platform for professional care coordination and communication with overview of patient's plans, consultations, and treatment
- Personal health technology for patient engagement

Stak  
hold

Supporting  
frameworks

### Technological solutions

- Integrated care platform for professional care coordination and communication with overview of patient's plans, consultations, and treatment
- Personal health technology for patient engagement

### Communicational and organisational solutions

- A continuum of workshops/forums with discussion, education and feedback
- Organizational agreements on structure, coordination and communication



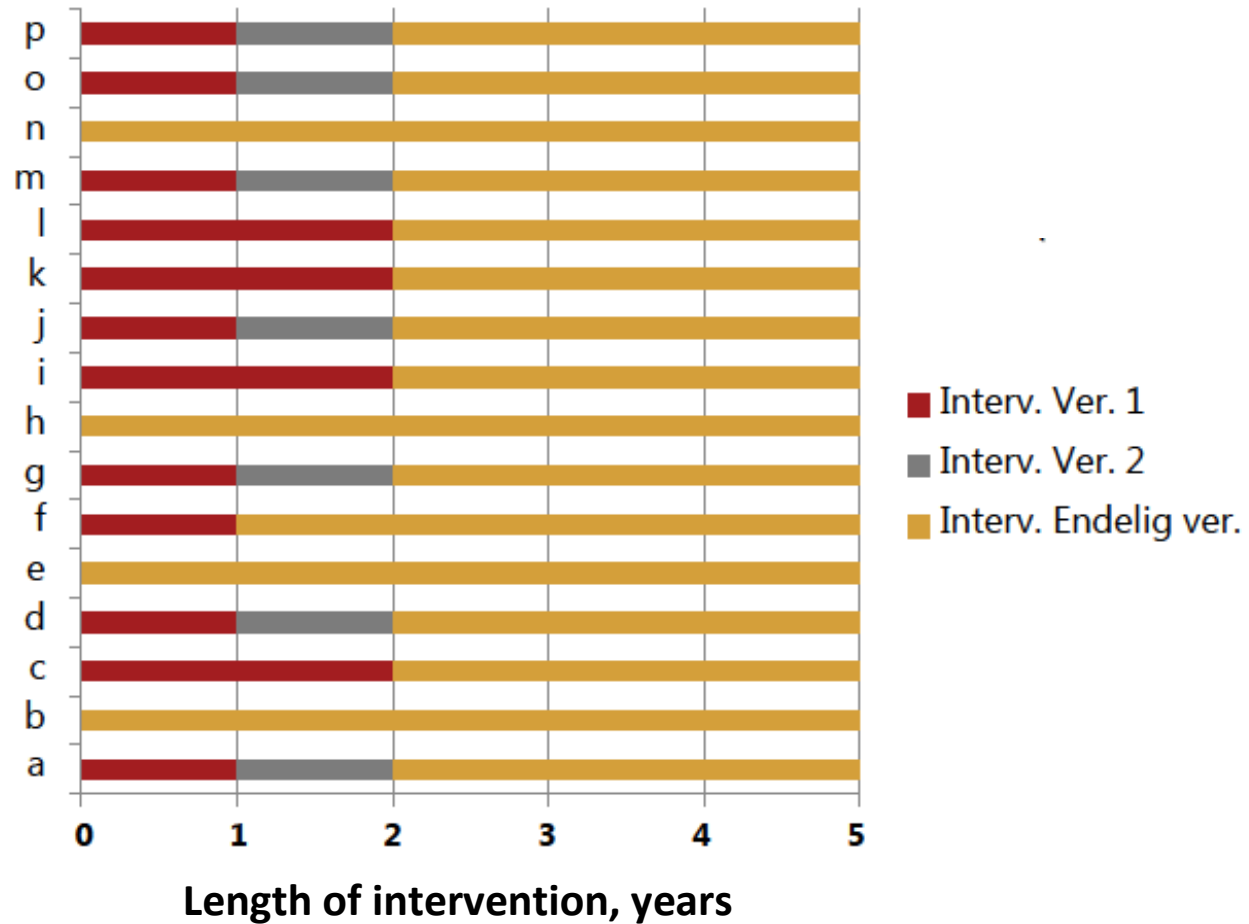
# Designing an adaptive trial

- The intervention is subject to change during the intervention period
- The adaptations will rest on accrued data from the process evaluation and experiences from external trials
- Valid statistical approaches will be developed according to accepted standards



# Adaptions in real life=?

The  
single  
elements  
of the  
inter-  
vention



# Evaluation

...to be qualified in the preparation phase

- Effectiveness
  - 5-year over-all mortality
  - QoL, physical function, labour market inclusion, hospital admissions, pharmacological treatment, treatment burden, treatment involvement and satisfaction,...
- Process
  - Intervention delivery and adoption, change mechanisms, user experiences, organisational prerequisites for implementation,...
- Cost effectiveness



# Broader perspectives

The Phy-Psy Trial will contribute to the development of:

- a **treatment model for complex patients** with several chronic diseases
- the “**near**” **health care services** that are closest to citizens and patients
- methods for **designing multifaceted, pragmatic/ adaptive RCTs** by creatively combining quantitative and qualitative methods





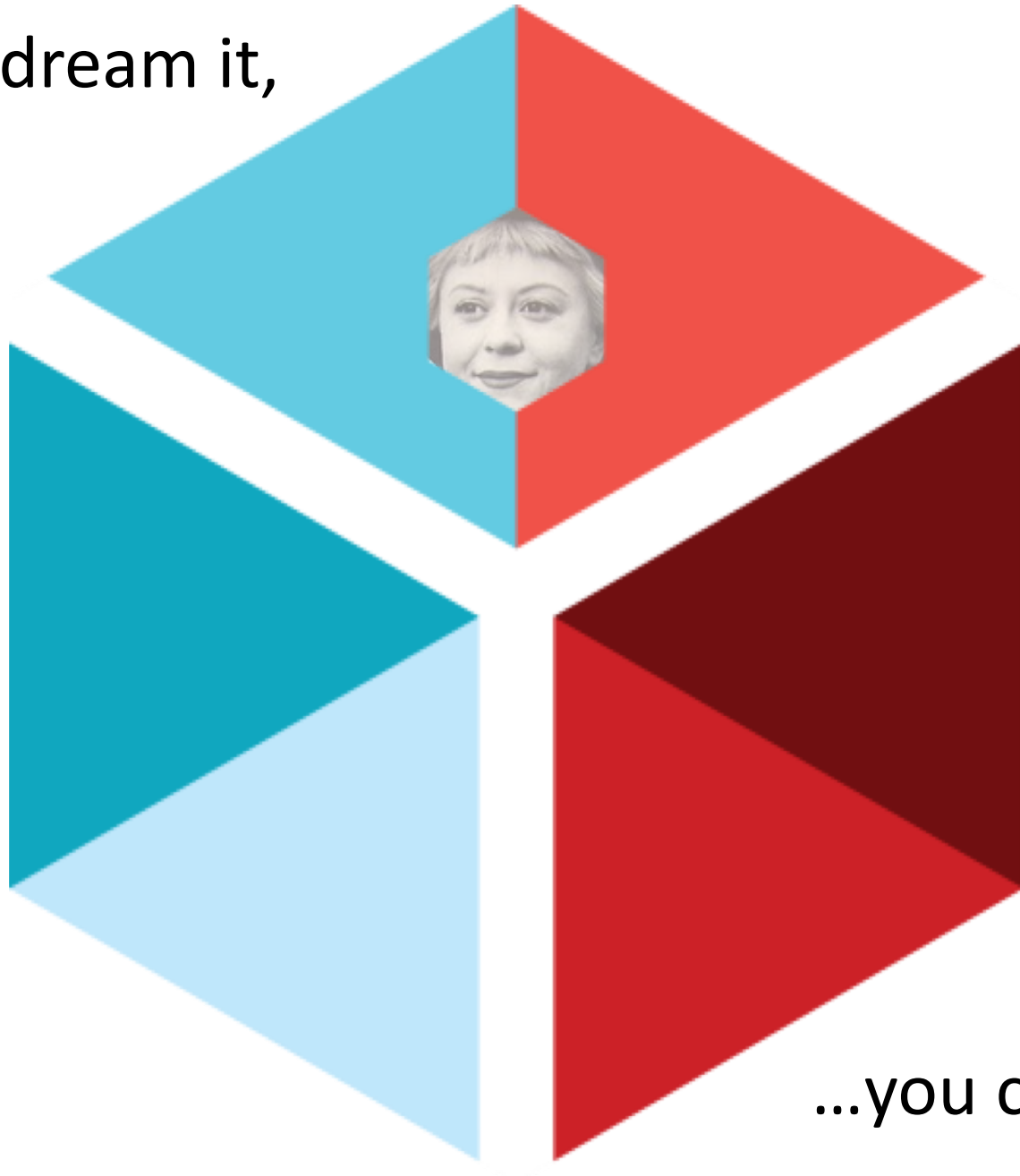


W. Eugene Smith  
*"Country Doctor"*  
1948



Giulietta Masina  
som Gelsomina  
i *La Strada*  
1954

If you can dream it,



...you can do it