synergus RWE
evidence for decicons

Project : How does digital solutions in mental health transform healthcare?

- What are the barriers and opportunities?
- What are the clinical and economical evidence requirements?

1   Introduction

This project is initiated internally by Synergus RWE and does not have any external financing. We do this project because we want to generate insights in how digital solutions in healthcare are being introduced / evaluated and paid for. We believe that there is a need to find complementary methods in how digital solutions are assessed compared to drugs.

2   Project dissemination

The primary out-put of the project is the Master Thesis for Shuchesmita Das in our health economic studies. If feasible the results will also be published in a scientific paper.

Throughout the project we will also share insights from the projects regarding:

- The characterization we do of the companies / interventions based on public information. This will be shared in similar outputs such as the initial report done:
  https://public.tableau.com/profile/mattias.kyhlstedt#!/vizhome/MentalHealthOverviewofDisease ManagementTools/Overview
- Summary conclusions based on the data in the questionnaires. We will not share any information that can be correlated to a specific company.

3   Context of analysis

3.1   Why a European context may be relevant for a US company

The focus of this study is reflecting the way healthcare is being assessed in Europe. This can either be relevant if you consider providing your services in Europe or if the US adapts similar evaluation methods. There has been an increasing use of Health Technology Assessment in the US for Medical Devices, which generally reflect the methodological framework we refer to in this evaluation.

3.2   Health technology assessments for digital health solutions

In most western European countries, processes have been established to assess if the benefit of new interventions can justify the cost of introduction.

This assessment is typically carried out by Health Technology Assessment (HTA) organizations, who follow very strict methodological requirements in their assessments. Typically, they will only include well designed Randomized Clinical Trials in the evaluations.

This practice is established since a long time for drugs. In the recent years the use of HTAs have increasingly been used to evaluate medical devices and diagnostics. The experience from industry is that the model applied for drugs is not quite relevant for devices and there is an ongoing debate about how to apply appropriate methodology.

The area of digital health has up until now received limited attention by the evaluators and there are limited frameworks in place.to support such evaluations. The MAST framework provides an adoption of the EUnetHTA (European HTA collaboration) framework to digital that gives some guidance in how this may look in the future.

Even though the frameworks for evaluations are not yet in place, one can expect that they will come and that the companies who develop the strategies to develop the anticipated evidence will be the winners of tomorrow.

4   Traditional clinical studies vs Real World Evidence in mental health

4.1   Traditional perspective about clinical evidence with a focus on internal validity

In the evaluation of new interventions, the historical focus has been to perform studies which have high internal validity to ensure that there is evidence to the effect of a drug. This data has then been extrapolated to a health economic result.
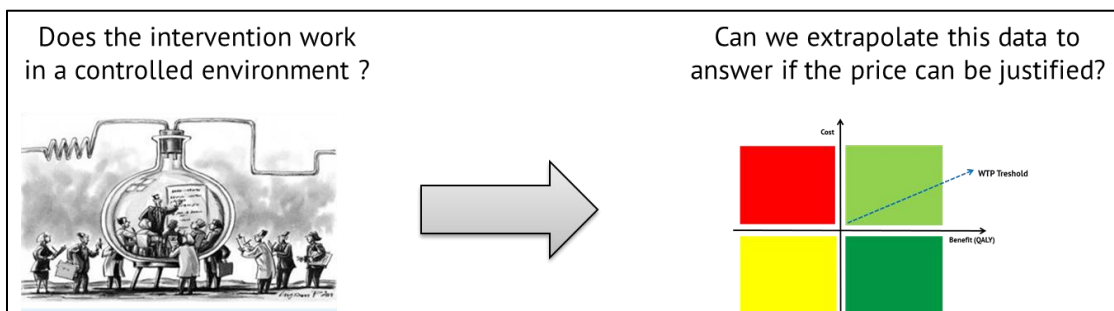

This approach has an important function in the evaluation of mental health to understand the different interventions. However, it has a limited value in understanding how well the intervention works in real life.

4.2   Perspectives on outcome research of digital health solutions in mental health

In the planning of this project we hypothesized that it may be relevant to perform real world evidence studies to provide decision makers with the relevant understanding of the effect and cost associated interventions.

4.2.1   Complexity of measuring the intervention

The effect of an intervention depends on several factors relating to the base-line characteristics of the patient (see below illustration) in combination with the subjective selection of a psychologist / psychiatrist. It is not infrequent that more than one intervention is provided concurrently. While observing the biologic reaction of a drug, there is less factors that will impact the effect. However, while looking at many of the digital interventions which aims for a response by the patient, the base-line characteristics of the patient and the ability to change are essential for the outcome of the intervention.
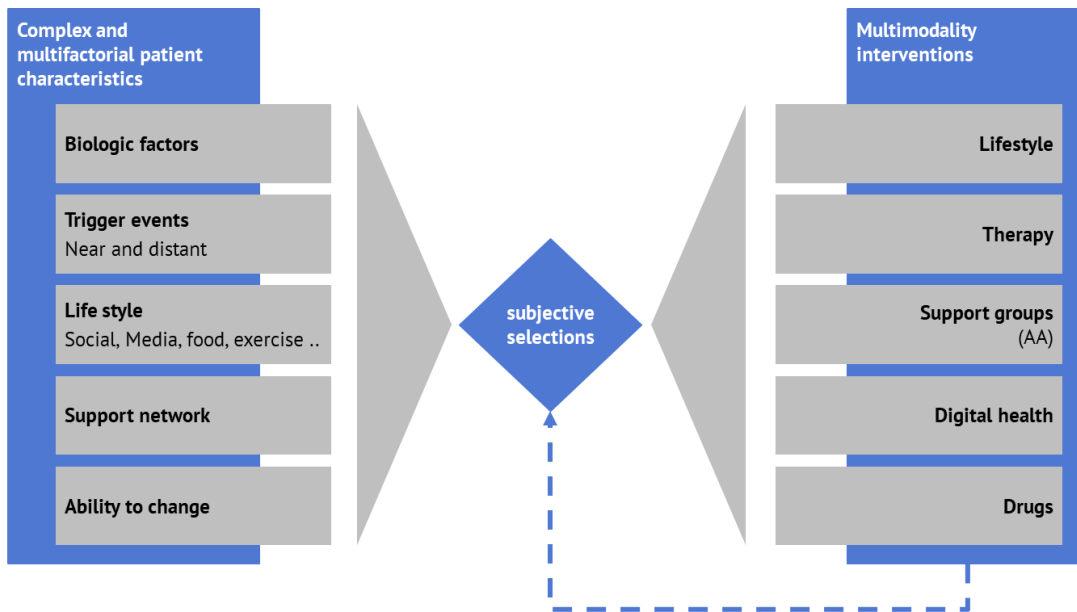
4.2.2 Questions of consideration in the evaluation of mental health applications

4.2.2.1 What is the relevant outcome to measure?

The traditional measure to evaluate the effect of drugs is the impact on the quality of life such as measured by EQ-5D or SF-36. The way these questions are shaped has clear limitations in the ability to address the dynamics. There is a growing trend to develop more holistic variables to assess the disease. One example is what has been developed by ICHOM which gives a much broader perspective adapted to the specific issue to depression / anxiety.

4.2.2.2 How do you observe the single effect of a single intervention in a multimodality intervention?

What is the appropriate methodological approach to evaluate to evaluate the effect of a single intervention, when it frequently is carried out concurrently and / or in sequence with other treatments? This complexity would suggest that there would be of value to use real world evidence to monitor the care pathway to enable evaluation of the different interventions.

4.2.2.3 How do you evaluate the quality of the selection of intervention?

The method of selecting the intervention for the right patient has a significant impact on the result. Even though this can be supported by methodology and assessment tools, it is rather subjective. How should the impact of this be captured in the evaluation?

4.2.2.4 How do you correlate the base-line characteristics to the result?

The base-line characteristics of the patient are crucial to understand how different patient respond differently to different treatments. Studies should aim to identify correlation between base-line characteristics of the patient, the selection of the intervention in order to give the relevant understanding of the effectiveness.