

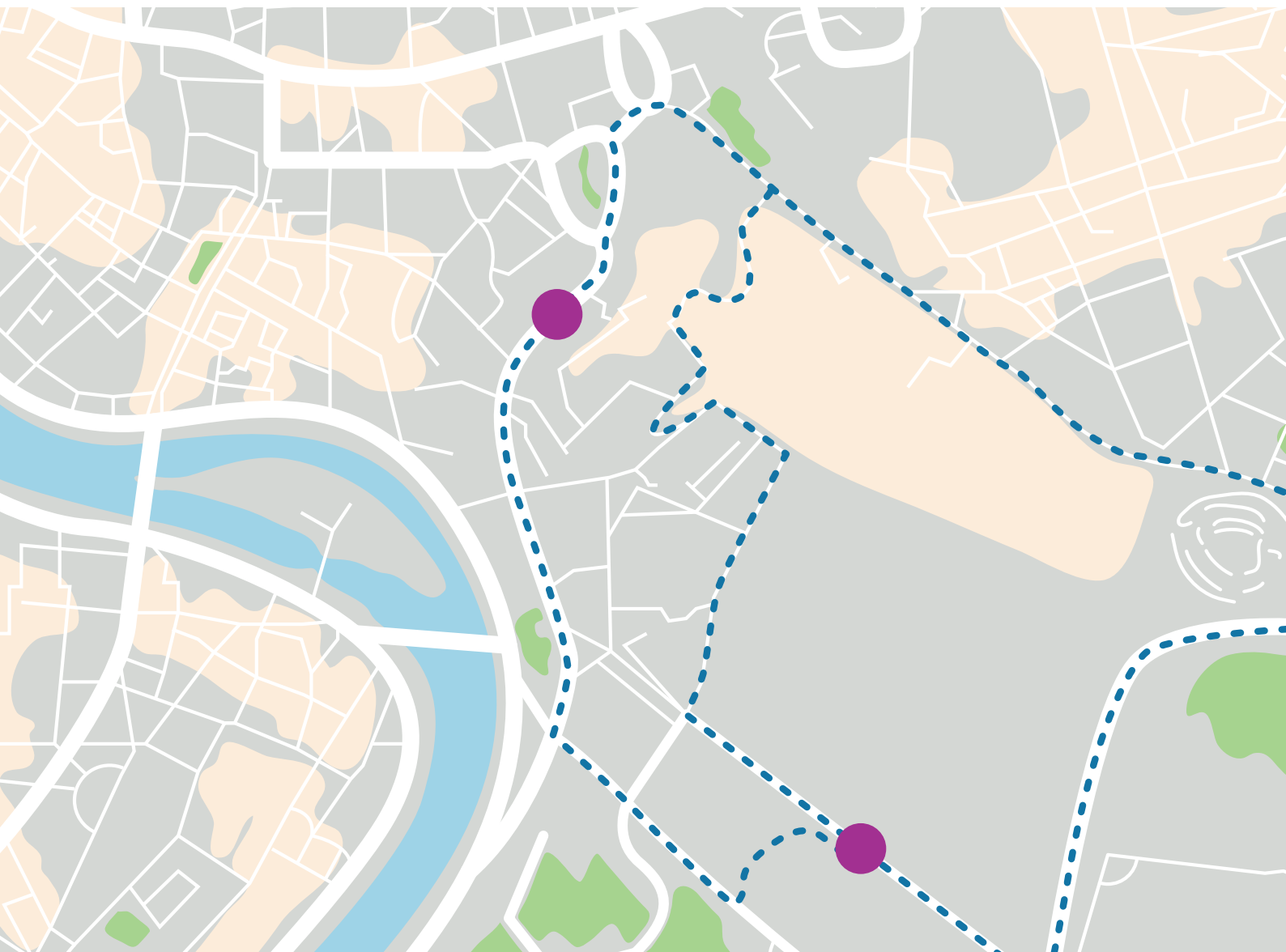


minddistrict

Developing the bespoke digital therapeutic

A fresh look at validation and the application of data in digital healthcare.

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Introduction

In this whitepaper, we take you through the realm of digital therapeutics, and show you how we aim to offer personalised medicine. Yes, that seems like a lot of buzz words in one sentence. And we didn't even use 'data' yet.

But we are serious. Our goal is to develop digital therapeutics, that can adapt to the actual needs of a patient at any given moment. A truly bespoke route to recovery.

Data is the key ingredient here. We strongly believe that the right application of data can take the world – and in our case healthcare – a step further. The subject of data can give people an insecure feeling though.

Who is doing what with which data? Not every company or government leads by example...

But data can also bring a lot. And transparency on data policy, being open about intentions and what we do, that can generate trust. That is exactly what we aim to do in this whitepaper. We will show you what it is we're doing to make data work for patients and their caregivers.

What you can expect in this whitepaper:

- Why personalised digital therapeutics? We'll explain the goal with the help of a metaphor and show what patients and caregivers can gain.
- We discuss another look at validation, what we are doing to realise our views.
- We'll look into opportunities of data collection and working in networks.

Finally, we'll wrap up our take on the contents of this whitepaper for you.



The GPS metaphor

We aim for personalised digital therapeutics. But what do we mean by that? And why is it our aim? This might be best explained with a metaphor: finding your way through the maze of city streets.

You can find your way with a classic map. If you look at healthcare today, that is what professionals and patients are using to get from A (where they are), to B (already feeling a bit better), to C (creating a relapse prevention plan) in treatment. You pick a destination and look up how you can get there: in two straight lines, zigzagging through the streets, or a combination of these. You'll often have an extra

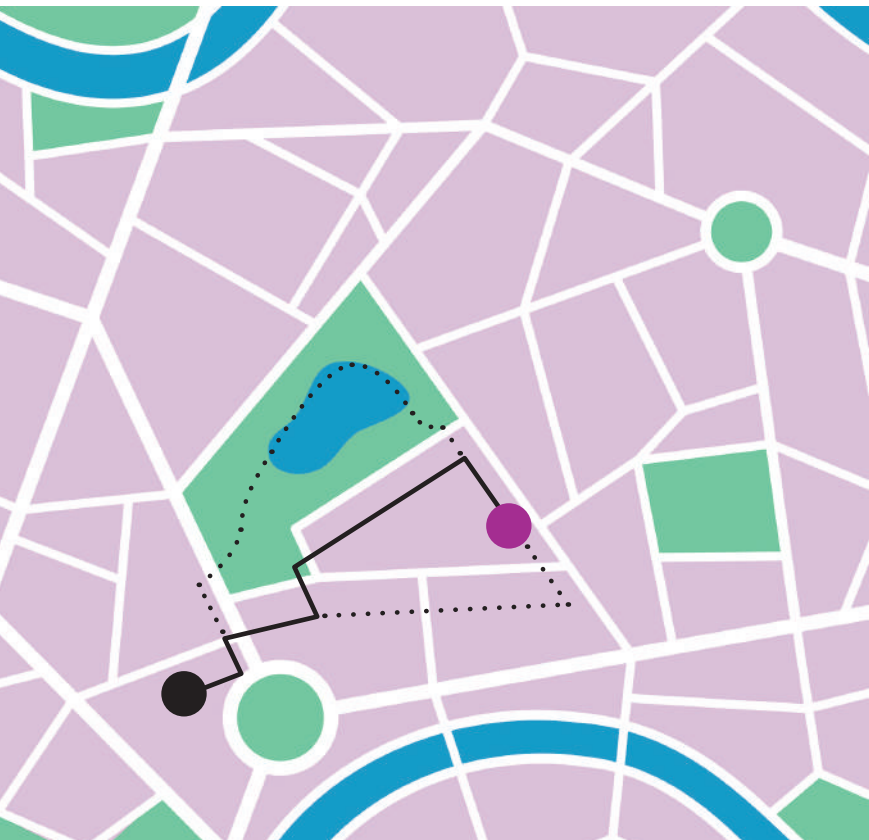
look on the map, for example when you encounter construction work, or a dodgy alley you'd like to avoid.

If you use GPS, the calculation of your route is automated. It knows about traffic jams and suggests alternatives to avoid them. It recalculates your route if you have missed a turn. And if you want to turn right instead of the suggested left-turn, you can, and the GPS adjusts accordingly. For all the suggestions and adjustments it makes: you are in control.

At Minddistrict, we aim to be your GPS – and a bit more.

Healthcare is about people getting better. And professionals, in the interaction they have with patients, have an important role to play. But even experts need tools. We aim to provide both patients and professionals with these tools, enriching and supporting the road to recovery. Making the lives of both patient and professional easier; whether that means 'not bothering them when the patient is on track' or 'assisting in case they get lost'.

This personalisation is hard. But it's the goal. In order to get to the point where we can suggest the best next action for a given client, we need to find the patterns on the map. Get to know the short stretches of street. We need to validate small blocks of content.



A fresh look at validation

We believe that effectivity is essential in digital healthcare. This is why the Minddistrict interventions are evidence-based. Our intervention developers use the Intervention Mapping method and conduct meticulous research into evidence-based methods and theories as part of the development process.

It is also why we're proud of our collaborations with universities and researchers of note, resulting in high quality, validated interventions such as digital STEPPS-EI, MyDiaMate, MindReSolve and the Dutch ACT-module 'Van klacht naar veerkracht' (literally translated to English, the title is 'From complaint to resilience'). The clinical trials attached to those interventions (usually RCT's, randomised controlled trials) are crucial in bringing health-care and digital interventions a step further. As Minddistrict, we will continue to pursue collaborations with top researchers in the field of psychology.

But we cannot solely rely on RCT's to realise personalised digital therapeutics, to reach the 'GPS' from the metaphor. For RCT's require the same intervention to work for a group of "average" patients. This will not bring you personalisation, rather the opposite. That is why this white paper proposes an additional approach to validation in e-mental-health. We are looking for an approach to validation that:

- Allows for rapid and continuous validation, so interventions can be quickly put into clinical practice;
- Allows for personalisation, aimed at validating smaller blocks of content.

Building blocks for our GPS

Personalisation of (digital) care has been our goal for years. The ehealth platform allows professionals to enable and disable chapters of modules, for example, or combine content to fit a patient's needs.

This is also why we create and promote transdiagnostic care. Because person A and person B might have the same diagnosis, but they might experience different symptoms. Their lives and environment are different, or they may have different styles of learning and practicing. So instead of giving person A and B the same digital intervention for the same diagnosis, patients and professionals can choose for transdiagnostic interventions as well. Modules and interventions that focus on specific complaints and dealing with them in a constructive way, or on goals a patient wants to achieve, or on removing an obstacle that stands in the way of recovery.

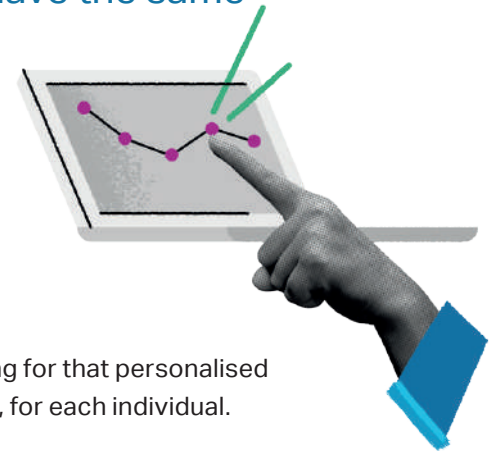
Choosing and combining diagnostic and transdiagnostic interventions, and being able to turn chapters on and off, already allows for a personal approach. But it's not a GPS yet: the platform doesn't show where you are, nor does it give an informed suggestion where best to go next.

Our approach also means the platform is able – and actually designed – to offer relatively small blocks of content. We want to move past the boundaries of a large, validated protocol, when, in a specific case, that particular intervention doesn't have the desired effect. We want to offer a platform that gives you the flexibility of offering alternatives that have better chances of working for your specific client, at a given moment, based on where they are in the process. That's why we're looking for additional validation.



The context of a network

We just established that person A and person B can have the same diagnosis, but experience different symptoms, or experience the same symptoms differently.



So how do you map out someone's symptoms?
How do you know how symptoms interact with each other? And where do you start?
This is where Networks enter the room.

The growing relevance of context

The world of psychotherapy often still focusses on 'healing' people who have become 'ill'. Though there is a clear trend that focuses less on absolutes and embraces context. For instance, healthcare professionals tend to approach mind and body as connected, not as separate entities. Acceptance is often seen as a very suitable way of dealing with challenges. And complaints aren't seen as existing in a vacuum. This last point, to us, is key in personalising psychotherapy.

By looking at symptoms as nodes in a larger network, you're allowing yourself to look beyond diagnoses. You'll also be able to get more insights into the relationship between symptoms. This doesn't just help assigning (transdiagnostic) interventions; it goes much deeper. The advances in data modelling make it possible to look at the likelihood of one symptom interacting with another, opening doors for a more tailored approach to psychotherapy.

Why do networks make healthcare more personal?

To avoid confusion: we're not trying to create a massive network of all symptoms based on all data available to us. In other words, we're not throwing everything on a pile. Because that wouldn't tell us anything about a specific person. It would result in a network relevant to the average person, which gives us the same limitations as an RCT.

We are looking for that personalised route by GPS, for each individual.

The data specialists of Minddistrict, who look at data in the context of validation, do think that networks can add value to the treatment of individuals. By smartly increasing the number of data collection points, we'll be able to map out a client's own network of symptoms. This allows the client and the professional to gain more insight into the way a specific client's symptoms interact with each other. Symptoms in the 'middle' of the network, with a lot of connections to other symptoms, could be considered important targets for therapy. If you reduce these symptoms, then the other connected symptoms may reduce as well. The use of networks has the added benefit of showing relationships between symptoms that the client themselves may not be aware of.

Amsterdam UMC is currently showing what networks can bring to the table: they use networks to decide which of Minddistrict's modules is best to assign to patients. The results of this case are positive. And it's interesting to think of what else can be done.

Once we start to discern interacting symptoms, we might compare these with trends in other networks, of people in a similar situation. Or – if a person has registered data entries for a longer period – we'll be able to look at earlier interactions of personal symptoms. These possibilities could help us to calculate the likelihood of a symptom appearing or intensifying, allowing for proactive support.

Measurements – making it all work

So, we want to find the patterns on the map, get to know the streets and crossroads from the metaphor. We want to validate small blocks of content. Networks can help us with that. The question that remains is 'how'. How do we get there? The answer? Data.

Data collection

By now, you've heard us mention it a couple of times in this whitepaper: increasing the number of data collection points. Using registered entries from patients. Data collection is the red thread throughout the journey to bespoke digital therapeutics.

But it is also a tightrope. Data collection cannot be too intrusive to a client, as you don't want to add to someone's cognitive load. You don't want clients to drop out because of the added effort needed to fill out questionnaires, to name one example.

So, what then? How can we increase the number of data collection points, without this taxation of someone's mental space? We admit that is tough nut to crack: it's what makes personalisation hard. But we are exploring the following routes.

Smart questionnaires

How can measurement be smart and less demanding? The first possible solution is the most obvious one: by keeping it short and simple. Mental health questionnaires are notorious for their length, difficulty, and, yes, high drop-out rates. If we want to increase the number of measurements, we need to reduce the number of questions considerably. This means we must bring the scope of a questionnaire down to the bare essentials.

Another solution can lie in high-frequency data collection over a limited period of time. In this solution, data is collected through a large number of measurements on a specific topic, in a specific timeframe that can sit before, during or after treatment. Think for example of collecting data over the first weeks of a waiting list. The methods of Ecological Momentary Assessment (EMA) and Experience Sampling Method (ESM) also fit in this approach.

Still, these approaches or methods can be quite taxing, especially considering they are meant for people who already are under the strain of psychological complaints. What would help is being able to only offer a questionnaire when it's most needed. Data modelling can help us out: a model can plot expected results of a question. Once the model detects that a result becomes more uncertain, more unpredictable, we can decide to add a specific question to someone's personal questionnaire. In this solution we offer nothing but the questions that really need to be answered.



The network approach could also be valuable to this solution, offering personalised questionnaires. For example, an individual's network could show that 'staying inside' is a clear indicator of mood-related complaints. In that case, you could reduce the number of questions about mental state, and simply ask how often the person went out today. Or, if we could do one better, just track movement. This brings us to the 'somatic department'.

Monitoring beyond the mind

The least intrusive way of monitoring is not having people fill out anything at all. Psychological complaints don't stay confined in the mind. In many cases, the body tells just as much. It can even be quicker, and reports without bias: your heart rate rises when you experience anxiety. You are less active, or don't move as much when you're down. And your sleep quality drops when you've been drinking alcohol.

This makes it worth to use wearables as a data-source. Our partner GGZ Delfland, a mental health organisation in the west of the Netherlands, are currently using wearables to monitor movement and sleep. Wearables are gaining popularity, more people are familiar with them. Simultaneously, wearables deliver increasingly more data: not just movement, but

also heart rate, sleep, and other functions. And that data is getting increasingly more reliable.

In this project, GGZ Delfland links lifestyle to mental health and wellbeing, and uses the network theory as a foundation for it. They have found that the clusters, or 'HUBs', in the network that have to do with lifestyle are connected to almost all forms of health. And between those HUBs, 'sleep' seems especially important.

That is why patients receive a wearable during their intake to track sleep. Monitoring is thus not only simpler for people, but also gives objective data. For example, someone who thinks they are a bad sleeper, might still get about 7 hours sleep.

The digital infrastructure needed for this project proved to be complicated for GGZ Delfland. But they have found ways to make it work. This example shows what is already possible, and offers a glimpse of what is yet to come.

In short

So, in short, how do we get to validation? We need an increased number of measurements, without alienating the patient, or adding to the mental load. The data coming from the measurements is the base for a trustworthy, continuing validation.



Pushing past the buzz

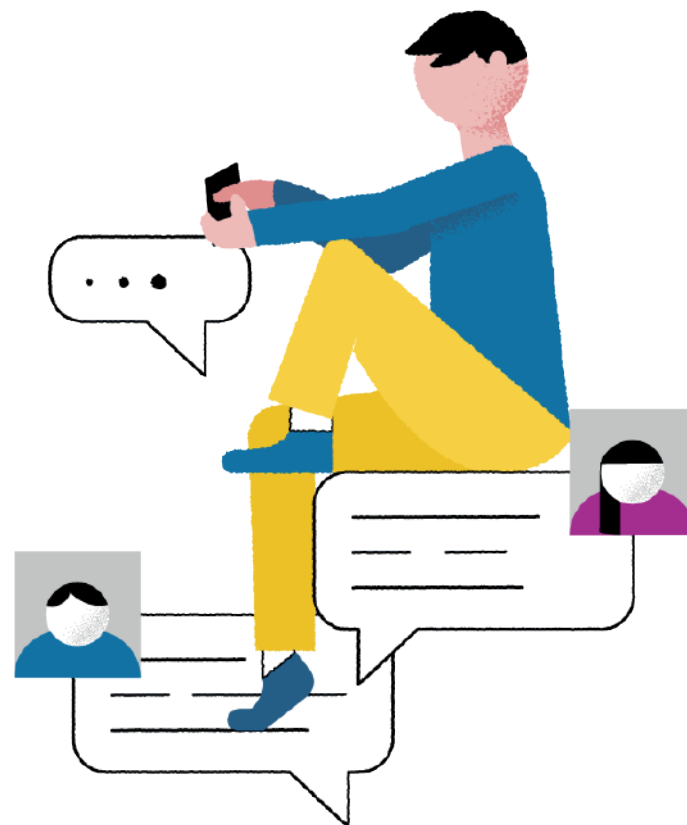
We'd like to wrap up with some thoughts on the buzz surrounding data and its applications. The dominance of big tech and the high marketability of the topic have given the world of data a close to religious status - people want to be part of it, people are fearful of it and people love to preach about it. The result is an ambiguous world, dominated by public relations. The practical discussion on how it can really benefit society and what implications that might have, sometimes feels pushed to the side.

We aim to take discussions on data to a different, more practical level. Earnestly talking about implications and limitations, aligning with stakeholders wherever we can. An approach already wonderfully brought to life by the Dutch AI coalition.

We feel that personalised digital therapeutics should benefit people who need mental healthcare, supporting not business, but society. That's also why we care about regulation, about the parameters that initiatives such as the AI coalition set. We need to keep discussing how our use of data is going to help patients and professionals.

And even though the progress might seem slow, this is the way we want to go. As we're building a flexible, personal GPS that truly helps caregivers and their patients.

Will you help us push past the buzz?



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Will you help us push past the buzz?