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Summary D8.3 Market Analysis and Strategy

In this report, we first provide brief background information on our DMMH tool. Afterward, we start with a broad market analysis of the mHealth market. Following this, we estimate the specific market size for the DMMH tool. Next, we provide results from a PESTEL and SWOT analysis, and the results from applying porter's five forces framework to the mHealth app market for mental health. Thereafter, we share results from competitor analysis. In the last section of this report, we translate the results of our market analysis and propose potential market strategies for promotion, distribution, promotion, customer relations, and further product development.



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0. Background information

0.1. Mission and vision statements

Our mission?

To enhance person-centered mental healthcare.

Our vision?

To develop a monitoring technology that is able to provide practitioners with valuable insight into the daily lives of their clients and assist clients in gaining greater insight into/in obtaining an increased understanding of their own mental health.

0.2. Product description

We are developing a ‘Digital Mobile Mental Health (**DMMH**)’ tool — a medical device to support clients and practitioners in clinical practice. Our DMMH tool is a secure and innovative software solution for using the ‘Experience Sampling Method (**ESM**)’ in mental healthcare. The ESM is a structured self-report diary technique for assessing mood, symptoms, context and appraisals as they occur during daily life. During the course of several days, individuals are required to complete a momentary ESM questionnaire several times a day.

How ESM can help

1. ESM may strengthen client engagement and empowerment, as it identifies the client as the expert of his or her experience, which makes them active partners in their own treatment.
2. Self-monitoring through ESM may improve client self-management and recovery as it provides the client with a tool to improve their understanding of their own mental health problems, as well as to manage these problems more effectively.
3. ESM data may provide goal direction in clinical assessment and management of care, as the detailed, granular and personal information on patterns of associations between symptoms, key problem areas and their contexts will help clinicians to come to clear, actionable and personalized therapy goals as well as improve overall management of care.

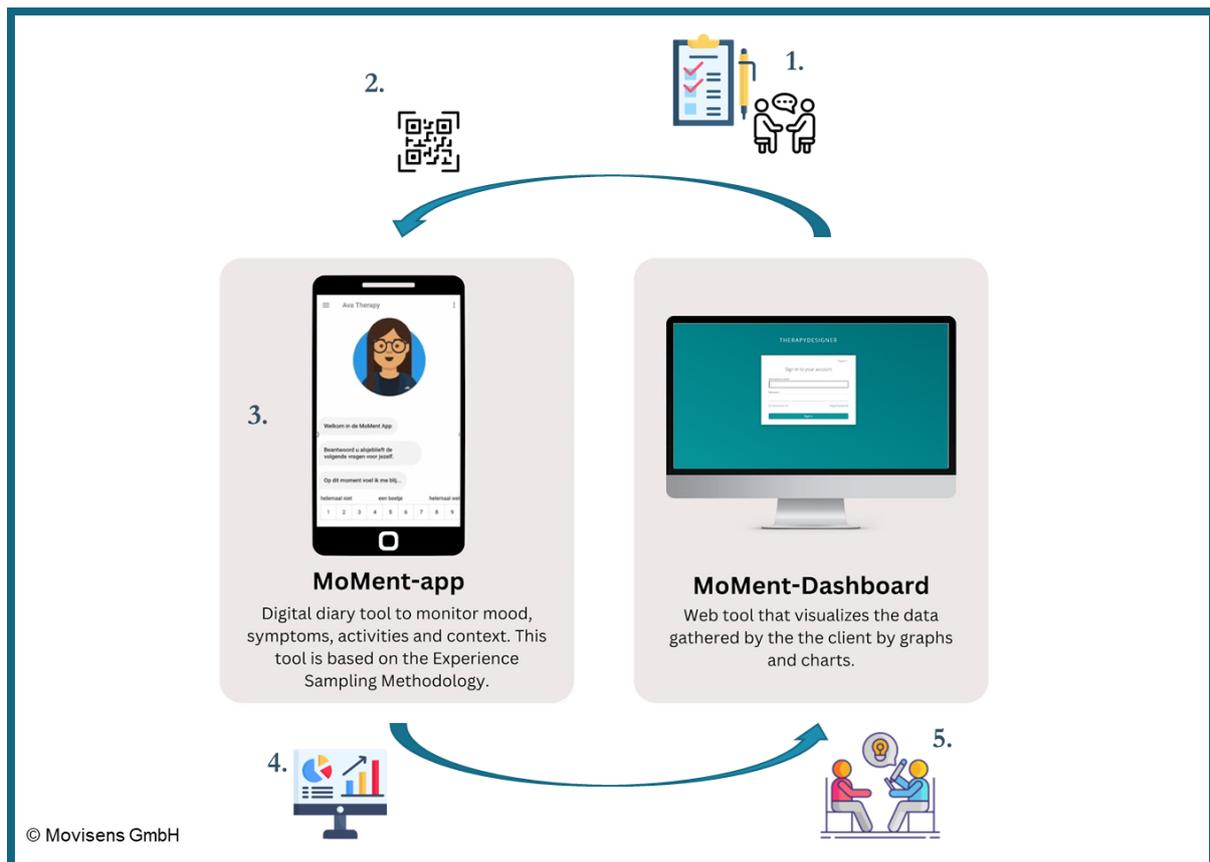


- ESM may enhance shared decision-making as it provides the highly needed relevant and qualitative day-to-day information on key problem areas and relevant contextual factors, which is needed for making treatment decisions and evaluating progress of treatment together.

The DMMH tool consists of a dashboard for practitioners and a smartphone app for clients. The dashboard is accessed through a website, whereas the app is simply downloaded from the app store. In addition, the dashboard provides practitioners with a template for creating an ESM questionnaire tailored to their clients' needs. Once created, a QR code is generated which clients can scan with the app on their smartphones. After that, the client simply fills out the tailored ESM questionnaire several times a day for a defined period. All the information collected this way, is subsequently visualized on the dashboard of the practitioner, so that the practitioners and their clients can use this information in therapy. In figure 1 below, we present an overview of the DMMH tool.

Figure 1.

Overview of DMMH tool.



1. Co-creation of ESM questionnaire. 2. Scannable QR-code 3. App for completing ESM assessments. 4. Automatic data visualization. 5. Use of visualizations in therapy

Practitioners will use DMMH (i.e., the product) throughout the flow of therapy (i.e., the service practitioners provide) to enhance the quality of care. This implies that practitioners provide clients with a technology-enhanced service (Anton & Jones, 2017) by using the DMMH. The DMMH situates itself in the **mHealth market**.



1. Market Overview

The mHealth market is a rapidly growing sector within the healthcare industry that is revolutionizing the way medical services are delivered. mHealth, or mobile health, includes the use of mobile technologies, such as smartphones, tablets, and wearables, to deliver healthcare services. mHealth products and services can provide remote patient monitoring, educational resources, and telemedicine capabilities, among other benefits. As technology continues to evolve, mHealth solutions have the potential to provide more personalized care and improved patient outcomes.

In this section of the report, we first attempt to provide insight into the global mHealth market size. To do this, we provide a concise summary of data that we extracted from existing market research reports.¹⁻¹⁰ Afterward, we make a more narrow estimate for the market size of DMMH-like applications specifically. For this, we follow an approach outlined by MaRs — a major player active in technology-related start-ups and scale-ups.¹¹

1.1. Market overview for mHealth: market research reports

We consulted 10 market reports.¹⁻¹⁰ These reports provide an overview of the broad mHealth market size. Market size, in these reports, is typically calculated as the sum of all revenue made from sales, for the reporting year, for mHealth products and services. The reports included segment information (e.g., apps vs. wearables) and also provided estimates for compounded annual growth rate (CAGR), a construct used to estimate how the total amount of revenue is expected to grow or decrease over a given forecasting period. Additionally, these reports provided information on geographical factors (e.g., the region with the largest market share and the region with the largest growth potential) and what factors may drive or impede growth. In what follows, we summarize extracted information.

What do market research reports tell us?

The first point of interest concerns market size estimates. The **median reported global market size estimate for the 2022 mHealth market was 57.3 Billion EUR, with a range between 42.1 and 120.1 Billion EUR.** These numbers, however, are to be interpreted with caution.



Specifically, the scope of included products or services in the consulted reports was broad, with the reported market size being an aggregate of the revenue made from monitoring apps, fitness apps, diagnostic apps, wearables, and so on. Similarly, these reports did not allow us to identify the percentage of revenue attributable to products like the DMMH intervention (i.e., limited access to segment data). Hence, **to get a more accurate idea of the market size for products similar to the developed DMMH, a more narrow approach is necessary.** We present such an approach in section 1.2.

The next interesting finding concerns the reported CAGR rates. The **median CAGR rate reported was 14,95%, with a range between 10.8% and 34,8%.** The length of the **forecasting period** for the CAGR was relatively similar between reports, with a **median of 9 years and a range of 6 to 10 years.** However, details on how the CAGR rates were calculated were not accessible for all but one report, in which the CAGR was calculated based on growth in the number of downloads in the ‘Health and Fitness’ app category. This is rather questionable as many apps are free (i.e., developers make revenue from ads), and are at the same time of low quality and lack an evidence base (Lui et al., 2017). Regardless, the reported CAGR rates across the various reports position the mHealth industry as a healthy market with significant growth potential. Similarly, **as the reported CAGR outperforms the average annual rate of return from broad market index funds (e.g., S&P500, ~ 10%)¹² and the current annual rate of inflation (e.g., EU, ~ 9%)¹³, it is an interesting sector for investors.**

Given the positive outlook the CAGR rates sketch (and limited insight into how they were computed), the next interesting question to ask is what may drive or impede growth in the mHealth industry. For this, we resort to reported factors that are thought to fuel or limit growth of the mHealth market, which we will label as ‘growth drivers’ and ‘growth limiters’ respectively. Reported growth drivers and limiters were largely similar across reports. **Growth drivers were presented in abundance** and include: COVID-19 pandemic and the need for digital health solutions — one report interprets the COVID-19 pandemic as an event that generated a ‘demand shock’; increased tendency to manage one’s own health; increased access/affordability to and knowledge of mHealth; increased investment in mHealth; supporting government initiatives; need for effective healthcare administration; increased patient involvement in healthcare. **Growth limiters were less prevalent in numbers, with issues on data privacy and paired regulatory affairs being, in most reports, the only limiter.** One report additionally included the increased need for interoperability and a slowly changing industry.



A final element to discuss that we can derive from the consulted reports concerns the geographical spread of revenue. Currently, most reports portray a similar story. Specifically, the **North American region is evaluated as generating the most mHealth revenue** (median reported value 40%, range between 37.1 and 42.1%), with **Europe closely on its heels** (only one estimate not behind a paywall, 33%). Despite its large population, Asia Pacific, is significantly behind (no estimates provided free of a paywall). Other geographical regions (e.g., Middle-East, Africa) generated limited revenue. The large market share of North America and Europe was attributed to increased consumer spending on healthcare and good access to mHealth and internet connectivity compared to other regions. However, **most reports identify Asia Pacific as the geographical region with the most potential for growth.**

1.2. Market Size for the DMMH intervention: MaRS approach

To calculate the market size for the DMMH intervention, following the MaRS approach¹¹, we need to 1) delineate different types of potential customers, 2) estimate how many customers exist per customer type, 3) determine the hypothetical penetration rate per customer type (i.e., the percentage of potential customers that would purchase the DMMH), and 4) determine the expected value of a sale, also per customer type. Afterward, we can express market size as:

$$\text{Market Size} = \sum_{n=1}^{\text{number of customer types}} (\text{Customer Type } n) \times (\text{Penetration rate } n) \times (\text{value per sale } n)$$

Thus, the market size is, in this case, the total amount of potential revenue for DMMH-like products. In what follows, we calculate this value. However, we limit ourselves geographically. Specifically, we only include large geographical regions (population >5.000.000) in which the DMMH can readily be implemented without needing additional translation work (i.e., countries where the mother tongue is either English, Dutch, Slovak, or German).

Customer types

In the process of delineating different types of potential customers (i.e., peer-discussion) we have come to identify **three different customer types**. The first type concerns **mental health practitioners and institutions**. Practitioners may purchase the DMMH through personal



funds. Institutions may purchase the DMMH through their innovation budget and provide it to their employed practitioners for use. This customer type is what DMMH is intended for. Next to mental health practitioners and institutions, we can also identify additional customer types that may benefit from using the DMMH tool. These include **medium- and large-sized companies** that may employ a psychologist or psychiatrist for assessing employee mental health and **universities and colleges** that may employ a psychologist or psychiatrist to provide students with mental healthcare. While these customer types are not the primary aim of the IMMERSE project, they form an interesting exploitation opportunity and will therefore be included.

Customer size per type

To estimate the volume of each customer type per country, we make use of **publicly available data**.¹⁴⁻⁶⁹ In an attempt to provide accurate estimates, we primarily attempted to **source data from governmental websites**; alternatives were used when unavailable. Results are summarized in Table 1.

Table 1.

Volume estimates per customer type

	Mental Health Institutions	Mental health practitioners	Companies	Universities and colleges
Belgium	118*	10.785 Psychologists 1.958 Psychiatrists	4.221 Medium 944 Large	73 Universities and colleges 279.145 Students
The Netherlands	2.042	15.000 Psychologists 3.500 Psychiatrists	9.200 Medium 1.880 Large	105 Universities and colleges 340.000 Students



Australia	161*	10.716 Psychologists 3.615 Psychiatrists	59.355 Medium** 4.533 Large**	43 Universities, number of colleges unknown 1.622.894 Students
UK	1.026	46.400 Psychologists 13.130 Psychiatrists	35.940 Medium 7.675 Large	285 Universities and colleges 2.182.560 Students
USA	12.275	181.600 Psychologists 25.520 Psychiatrists	36.3269 Medium 51.795 Large	3.982 Universities and colleges 19.400.000 Students
Canada	128*	19.591 Psychologists 4.770 Psychiatrists	22.725 Medium** 2.936 Large**	436 Universities and colleges 1.400.000 Students
Germany	738*	36.514 Psychologists 23.438 Psychiatrists	55.740 medium 11.317 large	422 Universities and colleges 2.950.000 Students
Slovakia	54*	295 Psychiatrists 287 Psychologists	1.129 Medium 224 Large	35 Universities and colleges 131.083 Students



TOTAL	16.542	320.901 Psychologists 76.218 Psychiatrists	551.579 Medium 81.304 Large	5.381 Universities and colleges 28.304.682 Students
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*does not include private enterprises

**Australia defines medium-sized companies as companies with 20 to 199 employees and large companies as companies with more than 200 employees. Canada applies a 100-499, 499+ criterion. These criteria differ from other geographical regions, in which the 50-250, 250+ criteria is used.

Note: Numbers reported in this table reflect the most recently available historical data that we could identify. They are, at best, interpreted as a rough estimate. True numbers are likely to be higher, provided that the mental healthcare industry is rapidly growing.

Hypothetical penetration rate

To determine the hypothetical penetration rate, we need to, for each customer type, consider whether the DMMH is a business product or a specialty consumer product. In the first case, the DMMH can be considered mission-critical and/or possibly recommended for use by mental healthcare organizations — similar to how heavily recommended and used SAP software is in the management of a business. For this type of product, we consider 10 to 40% as a favorable penetration rate. In the latter case, the DMMH is not mission-critical and is only used out of niche interest. In this case, we perceive 2 to 6% as a favorable penetration rate. Our estimates for favorable market penetration rates were based on expert recommendations.⁷⁰

For mental health institutes and practitioners, we chose to label the DMMH a business product. We made this decision based on our Phase I data report (D5.1.). Specifically, in Phase I, we collected data on whether practitioners find the DMMH beneficial and whether they have the intention to adopt it (i.e., Deliverable 5.1.). From this data, we know that on a scale from 0 to 100, where 100 corresponds to very beneficial, practitioners give the DMMH a rating of, on average, 65.1 (SD 21.7). Similarly, on a scale ranging from 1 to 5, where 5 corresponds to strongly agree, practitioners provide an average rating of 3.8 (SD=1.1) out of five. These data suggest that practitioners have a good intention to adopt the developed DMMH, or similar



products, in future mental healthcare services. For medium- and large-sized businesses, we chose to label the DMMH as a specialty consumer product. Specifically, while there is rising attention for businesses to provide mental healthcare services to employees⁷¹, we do not expect that psychological assessment of employees with the support of the DMMH or similar can readily become a mandated practice in the foreseeable future. Implied hypothetical penetration rates are summarized below. A similar rationale is applied for university students making use of mental healthcare services.

- For individual psychiatrists and psychologists and mental-health institutes, we assign a hypothetical penetration rate between 10 and 40%
- For medium- and large-sized companies, we expect a penetration rate between 2 and 6%
- For universities, we expect a penetration rate between 2 and 6% (i.e., 2 to 6 percent of students will make use of mental health services utilizing a DMMH-like tool)

Expected value per sale, per customer type

In this analysis, for each customer type, we interpret expected value per sale using a yearly licensing model in which the customer pays a yearly fee. We opted for this model based on our competitor analysis of close competitors (see section 5.). We define a broad pricing estimate using PwC estimates on the willingness-to-pay for an mHealth product (e.g., ~10 euro a month for a single user license⁷²) and comparison to close competitors (e.g., m-Path, ~50 euro a month for 10 licenses; Expiwell, increased pricing to businesses).

- For individual psychiatrists and psychologists, we propose a ‘practitioner license’, priced at €60-120. This license can be used with 50 clients and is valid for one year.
- For mental-health institutes, we propose a ‘practitioner-group license’. Pricing will depend on the number of psychiatrists and psychologists utilizing the DMMH tool within an institute. Can be considered a discounted individual license.
- For medium-sized companies, we propose a ‘business license’, priced at €600-1.200. This license be used by, at most, five unique users, with up to 250 clients.
- For large-sized companies, we propose a ‘business plus license’, priced at €2.400-4.800. This license can be used by, at most, twenty unique users, with up to 1000 clients.



- For universities and colleges, we propose a price based on the number of students we expect to use mental health services with the DMMH tool. We put the annual price per expected student-user at €1,2-2,4 (i.e., practitioner license has a limit of 50 clients and costs €60 to €120 annually → 1 client is €1.2 to €2.4 annually).

Result Estimates

Based on our broad estimates, our MaRs analysis suggests a market size range from ~€14.4 to ~€94.9 million for the developed DMMH or similar products. In Table 2 below, we summarize the results of the MaRs approach to estimate market size for the developed DMMH.

Table 2.1

Market size estimate for the DMMH tool following MaRs approach

	Customer Count	Penetration rate	Pricing	Estimate
Mental health institutes	16.542	0,1-0,4	*	*
Psychiatrists and psychologists	397.119	0,1-0,4	€60-120	From €2.382.714 to €19.061.712 per year
Medium-sized companies	551.579	0,02-0,06	€600-1.200	From €6.618.948 to €39.713.688 per year
Large-sized companies	81.304	0,02-0,06	€2.400-4.800	From €3.902.592 to €23.415.552 per year
Universities and colleges	5.381	0,02-0,06	*	*
Students	28.304.682	0,02-0,06	€1,2-2,4	From €679.312 to €4.075.874
			Total:	From €13.583.566 to



				€86.266.826 per year
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*No pricing or estimate available, see above

What do the results from the market analysis for DMMH tell us?

The results seem to suggest that the developed DMMH has a sufficiently large potential market size to attract investors. For example, the IMEC iStart program⁷³, a leading accelerator program for tech-related startups, is interested in startups that can generate a minimum revenue of 1 Million euros within a three-year timeframe. However, the results of our market analysis also indicate that the majority of revenue, despite a significantly smaller potential market penetration rate than our primary customer type, can be found by focusing on company-employed psychologists using DMMH for monitoring employee well-being in medium- and large-sized companies. Below, we further elaborate on this finding.

Alternative pricing model

In the results of the analysis outlined above, we bill the costs to practitioner / mental health clinics. The price practitioners or clinics would have to pay was based on what current ESM platforms charge and marketing consultancy firms recommend for mental health apps. However, provided we are uniquely developing the DMMH as a medical product, an alternative pricing method may be applied in which the costs are billed to the client as compared to the practitioner. This would entail that the DMMH tool is free for practitioners, but that if they use it with a client the client pays a fee — ideally reimbursed with health insurance (i.e., similar as to how the cost of kidney dialysis is billed to a patient, but reimbursed through insurance). When the current pricing costs are billed to the client, as compared to the practitioner, the potential revenue that can be made from our primary customer type is multiplied by a factor of 30 (assuming that, on average, each practitioner treats 30 clients yearly). This is summarized in Table 2.2 below.



Table 2.2

Alternative Market size estimate for the DMMH tool following MaRs approach

	Customer Count	Penetration rate	Pricing	Estimate
Mental health institutes	16.542	0,1-0,4	*	*
Psychiatrists and psychologists	397.119	0,1-0,4	€60-120 (x30)	From €71.481.420 to €571.851.360 per year
Medium-sized companies	551.579	0,02-0,06	€600-1.200	From €6.618.948 to €39.713.688 per year
Large-sized companies	81.304	0,02-0,06	€2.400-4.800	From €3.902.592 to €23.415.552 per year
Universities and colleges	5.381	0,02-0,06	*	*
Students	28.304.682	0,02-0,06	€1,2-2,4	From €679.312 to €4.075.874
			Total:	From €82.682.272 to €639.056.474 per year

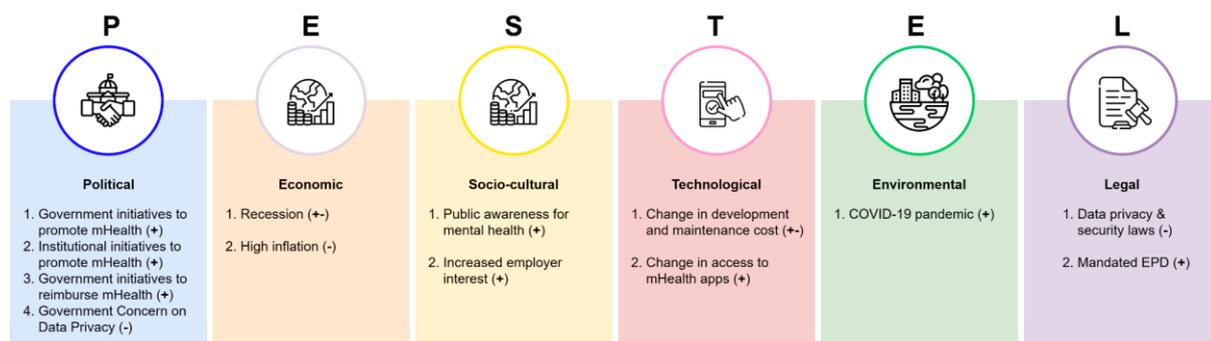


2. PESTEL

A PESTEL (also known as PESTLE) analysis is a tool to investigate macro-environmental factors (i.e., **P**olitical, **E**conomic, **S**ocio-cultural, **T**echnological, **E**nvironmental, and **L**egal) that may have an impact on the possibility to manage successful business endeavors within a given market segment. Factors identified in our analysis were drafted in collaboration with IMMERSE consortium members. Results are summarized in figure 2.

Figure 2.

Summary of the PESTEL analysis for the mHealth industry



2.1. Political

A first political factor concerns **government initiatives to promote mHealth**. For example, in Belgium, the government has set up a website on which it promotes mHealth apps that are CE marked as medical devices.⁷⁴ Similar initiatives exist elsewhere (e.g., Netherlands⁷⁵; Germany⁷⁶). Related are **Institutional initiatives to promote mHealth**, such as the ‘APP advisor project’ from the American Psychiatric Association.⁷⁷ A third political factor concerns **government initiatives to reimburse mHealth**. For example, in Germany the government has set up reimbursement pathways for mHealth.⁷⁸ In the UK, similar plans are being considered.⁷⁹ These first three political factors can be interpreted as positively impacting the mHealth business. A final political factor, and one that limits mHealth business, is **government concern on data privacy**, which can amount to new regulatory frameworks that require increased business spending to ensure compliance (e.g., GDPR, see legal factors).



2.2. Economic

The pressing risk of an upcoming **recession** is an economic factor that may have a positive effect on the mHealth market for mental health due to an increase in the prevalence of mental health problems. For example, Frasilho and colleagues (2015) conducted a meta-analysis of over 100 papers studying the effect of a recession on population mental health. They found that during such periods, a higher prevalence of mental health problems, including common mental disorders, substance disorders, and ultimately suicidal behaviour. Yet, a recession is also characterized by decreased consumer spending - which may negatively impact the mHealth market. Similarly, another economic factor that may decrease consumer spending concerns **high inflation rates** (i.e., reduced purchasing power).

2.3. Socio-cultural

In recent years, there has been a significant rise in promoting **public awareness of the importance of good mental health** (e.g., celebrity promotion⁸⁰ or tragic mental health related accidents leading to employment changes⁸¹). This is a first important socio-cultural factor that may have a positive effect on the mHealth mental health market. For example, increased awareness may lower the threshold for individuals to seek mental healthcare through mHealth apps. Another important, and related, social-cultural factor is **increased employer interest in the mental health of employees**. For example, several studies have shown that poor mental health has a negative effect on employee performance (Ratnawat et al., 2014), which may make companies eagerly interested in ensuring good employee health. Indeed, in a recent survey among employers, it was found that businesses have increased interest in providing mental health programs.⁸²

2.4. Technological

A first technological factor to consider concerns **change in development and maintenance costs**. Through optimization of software for making apps, the development cost of mHealth apps for mental healthcare may reduce in the foreseeable future. However, the necessity for the technology to comply with privacy and data safety standards may, in contrast, inflate development and maintenance costs. A second technological factor concerns a **change in**



access to mHealth apps. Mobile phone ownership and access to internet connectivity are rapidly increasing globally⁸³, implying growth for the mHealth market.

2.5. Environmental

A relevant environmental factor to mention is the effect of the **COVID-19 pandemic**. During the pandemic, mental healthcare services were digitalized as a necessity. This has had a positive effect on the mHealth market as it came with the necessary acceptance of digitalization amongst healthcare providers and patients.

2.6. Legal

A major legal factor includes novel **regulatory laws**. While they increase security and safety, they gravely shock the mHealth market. For example, the number of apps labeled as medical (excluding health & fitness) was 51,113 apps in the first quarter of 2018, and dropped to 32,984 in the last quarter of 2018.⁸⁴ This was due to the implementation of EU General Data Protection Regulations in May 2018. Today, this number has again sharply increased, with 54,546 apps labeled as medical in the third quarter of 2022.⁸⁴ These numbers demonstrate that the market is able to recover. The demand for mHealth pertains and developers manage to adapt to more stringent regulations, although additional costs are implied. A legal factor positively affecting the industry includes the call for mandated recordkeeping in electronic patient health files.

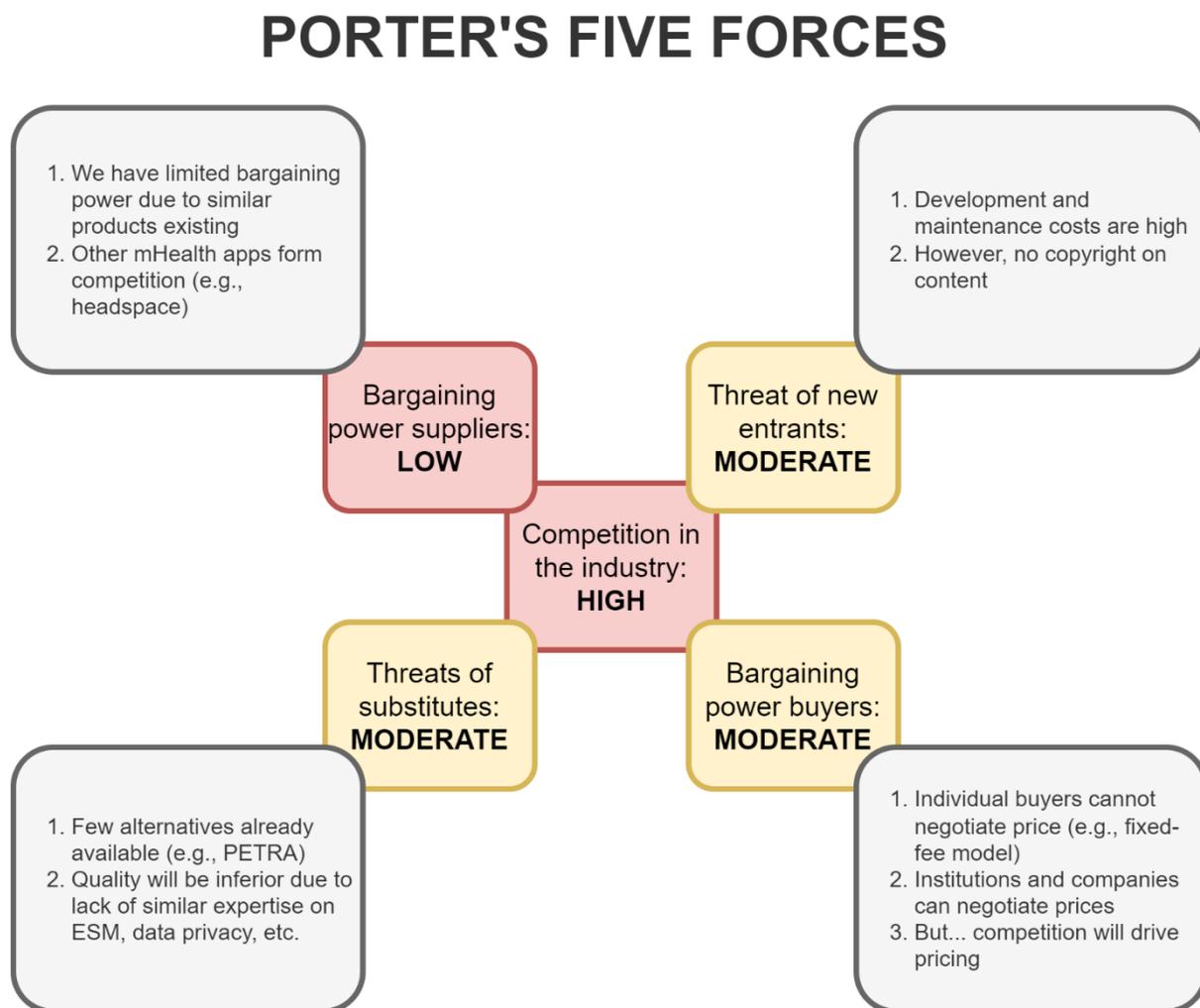


3. Porter's five forces

We utilize Porter's Five Forces framework (Porter, 2008) to analyze the competitive landscape of the mHealth market segment most relevant to the developed DMMH. The segment we focus on concerns the 'app' segment of mHealth. The five forces of Porter's framework include competition in the industry, the threat of new entrants, the bargaining power of suppliers, the bargaining power of buyers, and the threat of substitutes. Results were discussed with IMMERSE consortium members and external academics, a summary is provided in figure 3.

Figure 3.

Summary of the Porter's five forces applied to the DMMH tool



3.1. Competition in the industry: **HIGH**



There is a large degree of competition in the mHealth app market. For example, Shen and colleagues (2015) identified over 243 mHealth apps for depression. This is, unfortunately, not any different for applications providing services similar to the developed DMMH. For example, over 30 companies have been identified that provide Experience Sampling Solutions.⁸⁵ Currently, these companies focus primarily on academic use and are not labelled as medical products, which gives the DMMH a competitive advantage. However, some solutions offer an almost identical service (e.g., PETRA⁸⁶).

*3.2. Threat of new entrants: **MODERATE***

We consider the threat of new entrants as moderate. Specifically, the development and maintenance cost to develop a product similar to DMMH will require significant investment efforts. However, major corporations may enter the clinical experience sampling space and offer similar services as ESM questionnaires and statistical data visualization techniques are not copyrighted. One potential competitor that may expand into the experience sampling space includes Samsung Health, which is currently already used to monitor physical activity, diet, and sleep.⁸⁷

*3.3. Bargaining power of suppliers: **LOW***

As suppliers, we have only limited bargaining power. This is because our blended-care tool may have to compete with similar products (e.g., PETRA) and stand-alone products that are used and/or prescribed by practitioners to improve mental health. A popular example includes Headspace, which is a stand-alone mindfulness and meditation app that can help users reduce stress, improve sleep, and manage anxiety. Headspace, founded in 2010, made an estimated \$150 million in revenue in 2020, with 2 million subscribers and 65 million downloads.⁸⁸ Additionally, they managed to partner with over 2100 businesses.⁸⁸ These businesses provide the headspace app to their employees for free.

*3.4. Bargaining power of buyers: **MODERATE***

We consider the bargaining power of buyers as low. Buyers have many mHealth options to choose from, but can typically not negotiate better prices or more features from sellers (i.e.,



fixed-price license model). We predict that the price of the DMMH will instead be mainly driven by competition of similar competitors and/or stand-alone apps.

*3.5. Threat of substitutes: **MODERATE***

We consider the threat of substitutes for the DMMH as moderate. There are a few substitutes available that mimic the unique set of features of the developed DMMH. However, the development of additional substitutes would be a costly endeavor. Additionally, the level of knowledge required to develop a good Experience Sampling tool makes it unlikely that high-quality substitutes will emerge that can offer the same amount of quality, data safety, and regulatory compliance.



4. SWOT Analysis

We used a SWOT analysis to evaluate the **S**trengths, **W**eaknesses, **O**pportunities, and **T**hreats for the developed DMMH. The goal of this analysis was to identify both internal and external factors that may affect the potential success of a DMMH business case and how we can use this information to develop effective strategies for future valorization (i.e., part two of this report). Strengths refer to the positive attributes that the DMMH has, weaknesses refer to the negative attributes or areas needing improvement, opportunities refer to external factors that may be beneficial to the potential DMMH business case, and threats refer to external factors that may be detrimental to the potential DMMH business case. A concise summary of the SWOT analysis is provided in figure 4.



Figure 4.

Summary of the DMMH SWOT analysis.

DMMH SWOT ANALYSIS



4.1. Strengths

A first strength is that we are attempting to provide an evidence-base for benefits from using the developed DMMH in therapy (e.g., claims of increased patient engagement studied in our large-scale multicentric study). This is a major strength in comparison to other mHealth products, as the majority of mHealth apps available do not provide any form of evidence for



made claims (Peris, Miranda, & Mohr, 2018). A second strength is that we are developing the DMMH through a large consortium of healthcare professionals and respectable academics. Similarly, we included end-user feedback in an iterative development process. These aspects give our app a form of credibility and user-fit that competitors may lack as their products may not be adaptive enough to practitioners and clients needs (Eyles et al., 2016). A next point of strength is that the DMMH is easy to access, with few resources required. Specifically, practitioners only need a computer or tablet with internet access and clients need a smartphone; which holds true for the majority of individuals living in developed countries (e.g., several studies report smartphone ownership exceeding 90%; Hsu et al., 2022; Bell et al., 2022). A final point of strength is that the DMMH is being developed in compliance with medical device regulations. This will be a major strength as it demonstrates that the DMMH has undergone rigorous testing to ensure it is safe to use and effective. This is advantageous for users, healthcare providers, reimbursement agencies, and regulatory bodies. Additionally, it provides a competitive edge for marketing.

4.2. Weaknesses

A first weakness of the DMMH that we are developing is that the ESM questionnaires are currently not copyrighted, neither are the statistical techniques that we use to visualize data. A second weakness of the DMMH is that clients require a stable internet connection to receive notifications to complete an ESM questionnaire. A third weakness is that our consortium has little marketing experience. A fourth weakness we identified is that the DMMH lacks brand identity and a concise selling proposition for the DMMH is lacking.

4.3. Opportunities

With the rise of several governmental and institutional initiatives to promote mHealth apps that are evidence-based and secure (e.g., section 2.1.), the DMMH we are developing as a free-exposure opportunity. Another opportunity concerns the current partnerships with practitioners and institutions that are taking part in IMMERSE. Once the project comes to a close, we may have a selling opportunity to practitioners and institutions that want to continue to use the DMMH. A final opportunity to mention is that there is currently no market leader in terms of experience sampling software for practitioners. As ESM is not yet routinely used in practice, there is a competitive opportunity to create a monopolized position within the untapped market of using ESM as a blended-care tool.



4.4. Threats

The most important threat to mention concerns direct competition (e.g., ESM software that offers close to identical services). An example includes PETRA, which offers a similar IT infrastructure and is simultaneously also being developed by a large consortium of researchers and clinical experts. The next threat concerns new players entering the market. While initial development costs may be high, our non-copyrighted material can easily be stolen for development of a similar product by a business with enough capital. Another threat concerns novel regulatory frameworks being put into place following data privacy concerns. Specifically, in the worst-case scenario, this could result in major costs to update the software infrastructure. A final threat concerns the availability of practitioners to learn to use the DMMH software in their clinical practice. For example, in a recent pilot study, it was argued that clinical ESM software similar to our DMMH is usable and desired, but practitioners need not always have the time to learn to use such software (Weermeijer et al., 2023b).



5. Competitor Analysis

As indicated in Porter's five forces framework, the mHealth space for mental health is highly competitive. There are many competitors to take into consideration. In what follows, we provide non-exhaustive list of examples that we found through media articles, app-store ratings, and personal correspondence.

5.1. PETRA

PETRA (founded in 2021; Bos et al., 2022), which stands for 'PErsonalized Treatment by Real-time Assessment', provides experience sampling software for clinical use.⁸⁶ Their software is close to identical to the DMMH we are developing. For example, PETRA is also developed by respectable scholars in the field of ESM in collaboration with end-users. Similarly, their tool also provides the clinic with ESM templates that practitioners can modify in collaboration with clients. Collected ESM data is additionally visualized in a similar manner as compared to our DMMH visualizations.

PETRA is currently operational in mental healthcare facilities in the Northern part of the Netherlands. In these facilities, they have managed to successfully integrate their software into electronic patient file systems. They have informative videos about their software available on their website. PETRA is available in Dutch, albeit their website is also accessible in English. Arguments for using PETRA, in comparison to what we hope to do with the DMMH, are not based on evidence of improved care from a randomized-clinical trial. PETRA is currently not a commercialized product (i.e., no pricing information is available). PETRA does not have a medical device label.

PETRA forms a considerable threat to the market for our DMMH. However, if our RCT shows positive results, we will have a competitive edge. Similarly, the scope of their product is limited to the Netherlands whereas we are currently operational in the UK, Germany, Belgium, and Slovakia. This allows for a faster scale-up of the DMMH in comparison. However, they lack a medical device label. With increasing regulatory oversight, this may limit their scale-up and survivability.

5.2 *m-Path*

m-Path (founded in 2019) provides experience sampling software for clinical and academic use.⁸⁹ However, their approach differs from the DMMH or PETRA. Specifically, they do not



provide templates to practitioners. Instead, they provide software that practitioners can use to create templates themselves or share with others. Their software was developed in collaboration with ESM experts and is continuously improved through feedback or customer requests from academic institutions and/or practitioners. Their software offers possibilities for creating ESM templates (Weermeijer et al., 2023b), as well as ecological momentary interventions. Yet, significant time and expert knowledge is required to create or set-up an ESM template that would mimic what our DMMH can do. Visualizations for clinical use are available, but guidance on interpretation or use is lacking as compared to the DMMH. Nevertheless, m-Path is involved in several (clinical) studies, with their website citing projects in Belgium, Finland, Germany, Hong-Kong, Spain, and the UK. The m-Path software is commercialized. They use a freemium pricing model, with the free version allowing use with up to 50 clients. The premium model, for clinicians, is sold to mental health clinics for €500 per year. One clinical license gives access to 10 users, a three-hour training session, priority support, and advanced features. The m-Path software is not considered medical software.

m-Path forms a significant threat to the market for our DMMH. For example, they are already active in the mental health market space. Additionally, and perhaps most significant, is that their software architecture allows them to copy the ESM templates that we provide practitioners through our DMMH software without any additional software development costs. However, similar visualizations would require additional development. Nevertheless, provided there is no copyright on our ESM templates and data visualizations, m-Path could dangerously freeload on the results of our randomized clinical trial to create a substitute product. However, similar to PETRA, m-Path does not have a medical device label.

5.3 Headspace Health

Headspace health is a mental health company valued at ~€2,8 Billion.⁹⁰ The company is the result of a 2021 merger between Headspace (founded in 2010) and Ginger (founded in 2011). Headspace is a mindfulness stand-alone app and is available at €12,99 per month, or €57,99 annually (i.e., €4.83 per month).⁹¹ Ginger is an app for on-demand mental health services.⁹² As the Headspace app can be considered a stand-alone product, we focus on the Ginger app. The services of the Ginger app include 24/7 text-based behavioral health coaching, one-on-one video therapy or psychiatric care, and self-guided therapy. Ginger has contracts with businesses and universities. Through these contracts, businesses and universities provide free access to the



services of Ginger for employees and students respectively. What companies and universities pay Ginger is not publically disclosed. However, in a leak from 2022, information from a US company quote suggests a price of ~€3100 per employee, per year.⁹³ Currently, Ginger mainly operates in the US. However, through their partnership with Headspace, they may expand to other markets (i.e., Headspace is already available in 190 countries). Headspace health had ambitions to become a digital therapeutic (i.e., medical product that can be reimbursed) in 2018, but have not yet obtained a medical device label.

Headspace Health has access to funds that would allow it to easily and swiftly create a substitute product for the DMMH we are developing. Through their Ginger app services, they simultaneously have access to a large number of practitioners that they could train to use ESM. They are not a medical product, but could utilize funds to fast track this process.

5.4 Calm

Calm (founded in 2012) is a mental health company that is known for its mental health app on sleep, meditation, and relaxation (i.e., sleep stories — stories narrated by celebrities to fall asleep to).⁹⁴ It is valued at ~€1.88 Billion, made ~€188 Million in revenue in 2020, and has over 4 million subscribers.⁹⁵ The Calm app is priced at €49.99 annually (i.e., 4.16 per month) or €349.99 for lifetime access. In 2022 Calm developed ‘Calm Health’, which is a mental healthcare solution for businesses that provide employees with mental health programs, access to therapeutical sessions, and medication tracking.⁹⁶ The pricing of Calm Health to businesses is not disclosed publically. Services provided by Calm are evidence-based, with their website citing over 25 peer-reviewed publications. However, their app does not have a medical device label (i.e., the app does not provide a service, it enables service).

Calm is similar as compared to Headspace Health in terms of competitive threat. They have access to considerable funds and practitioners. Additionally, their Calm Health product has a global reach, with the volume of current partnerships exceeding over 3,000 organizations globally.

5.5 Thriveport

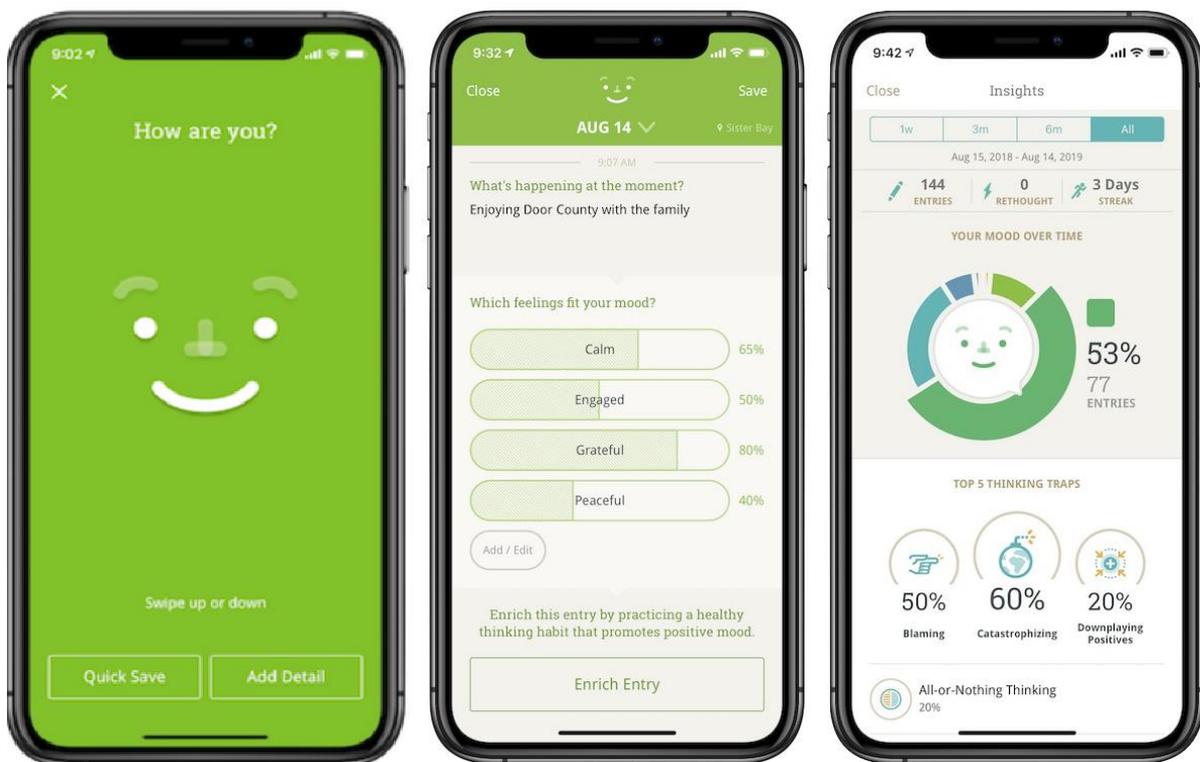
Thriveport (founded in 2010) is a mental health company that provides apps to improve quality of life.⁹⁷ The apps they have in their portfolio include MoodKit, Moodnotes, and Sleepzy.



MoodKit is a self-help app applying cognitive behavioral therapy principles, MoodNotes is a personal diary app for tracking mood, and Sleepzy an app for improving sleep. Out of these three apps, MoodKit is the only app for which they provide evidence that it improves mental health (i.e., randomized controlled trial; Bakker et al., 2018). The MoodNotes app is the app that most closely resembles an ESM app (figure 5). Specifically, users get reminders to complete their diary similar as to how we notifications are used to complete ESM questionnaires. The assessment is brief, with users needing to complete ESM-like items (i.e., a smiley with 5 options ranging from ‘very sad’ to ‘very happy’ or a question on rating various mood items in response to the context someone is in). Users can also add free text or pictures to a ‘mood note’. Collected data is aggregated and visualized in the app. The app is priced at €43,99 per year. Thriveport made an estimated 4.1 million in revenue in 2020⁹⁸, newer data could not be identified.

Figure 5.

Moodnotes application.



Retrieved from <https://thesweetsetup.com/apps-we-love-moodnotes/>

Unlike Headspace Health and Calm, Thriveport is not yet invested in using their product as a blended-care tool. However, their Moodnotes app closely resembles an ESM app



and could be further developed or marketed. However, as they appear to have limited association with practitioners the threat of this is much lower as compared to the threat of a substitute products from m-Path, Headspace Health or Calm.

5.6. Health monitoring apps of multinational smartphone developers

Samsung Health (released in 2012) is a free software application developed by Samsung (founded in 1969).⁸⁷ It is used to track various aspects of daily life, including physical activity, dietary monitoring, and sleep. It is installed by default on some Samsung smartphones. Apple (founded in 1976) provides a similar product, installed by default, for iOS smartphones, called Apple Health (released in 2014). Both products focus predominantly on passively collected data, which concerns data such as the number of steps per day, heart rate (measured with a compatible smartwatch), and so on. Moreover, Apple has medical device labels on their products.

While health monitoring apps of multinational smartphone developers do not mimic the DMMH or similar products, they do show that these multinationals have an interest in providing health-monitoring technology to their end-users. As companies are always trying to evolve, it would hence not be unsurprising if these multinationals decide to work towards blended-care solutions. For example, Apple Health (medical device certified) already allows the integration of medical records in Canada, the UK, and the US. Similarly, it is possible to share these health records with healthcare providers in the US.

5.7. QIT online

QIT online (founded in 2013) is a Belgian software platform with two main services. The first service it provides concerns a dashboard for practitioners that digitalizes many elements of standard mental healthcare practice.⁹⁹ This includes the possibility of documenting and using psychodiagnostic tools, screening tools, and routine outcome monitoring tools. Similarly, QIT offers documentation options for reporting and reimbursement. The dashboard for practitioners is priced at €15 per month plus €5 per new client, or €39 per month with no added cost for new clients. A 20% discount is applied if a year plan is purchased. The second service QIT online provides is for companies and individuals interested in improving their mental health and concerns self-help modules validated through academic research. Practitioners can also use



these services in therapy if they pay an additional €20 per month. Total revenue and pricing to companies and individuals could not be identified.

QIT online does not currently offer the use of ESM, but its digitalizing role in recordkeeping gives them a competitive advantage. Specifically, in Belgium, it is by law required to keep records of people using mental healthcare services. These records will, furthermore, need to be kept online in the foreseeable future (i.e., awaiting a royal decree). As practitioners and mental healthcare facilities may be reluctant to use a plethora of different digital health systems, it can become difficult to provide additional digital solutions. Similar scenario's may occur in other countries. For example, the European Commission published a report in 2016 on national laws surrounding electronic health records in which they state that legal mandatory use of such systems is likely to increase across member states in coming years.¹⁰⁰

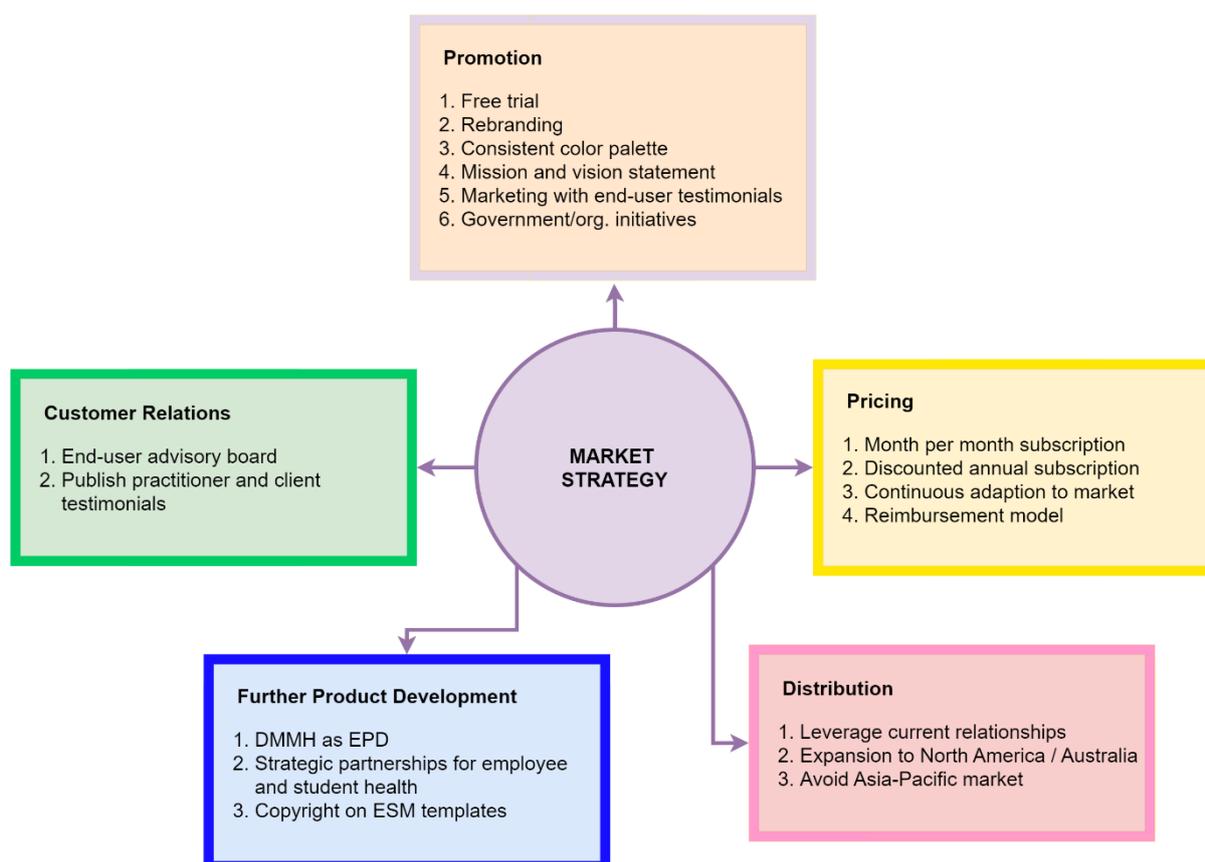


6. Market Strategy

In this section of the report, we outline a marketing strategy for the DMMH. In this strategy approach, we integrate information outlined in sections 1 to 5. Suggested strategies to explore are summarized in figure 6.

Figure 6.

Summary of market strategy.



6.1. Is it feasible to market the DMMH?

The mHealth market for mental healthcare apps is an industry with significant potential for growth (cf. section 1.1.). Macro-environmental factors surrounding growth appear favorable (cf. section 2.). The total amount of potential revenue the DMMH could make appears to



suggest that it is feasible to market the DMMH (cf. section 1.2.). However, to maximize potential revenue it would be best to investigate the marketability of the DMMH as a reimbursable medical product that can be billed, through reimbursement, to the client. Similarly, it may be advantageous to investigate the use of the DMMH for other purposes than originally intended. For example, as compared to the primary aim of integrating the DMMH within clinical settings, an expansion to other settings — such as providing mental health assessment for employees and/or university students (cf. section 1.2.) — is favorable. Yet, an important caveat is that the mHealth market for mental health care apps is an exceptionally competitive space. This is problematic as big market players have the capital to create substitute products or act as barriers to new entrants (i.e., DMMH) trying to gain market share. Similarly, the threat of other new entrants exists (e.g., PETRA). Hence, it is important to evaluate and develop strategies on how we can improve, promote, price, and distribute the DMMH if the results of the randomized clinical trial are in line with our expectations.

6.2. Promotion

A first market strategy for promotion concerns offering a free trial. While practitioners may be familiar with stand-alone mHealth apps to improve mental health, we expect the current amount of practitioners actively using blended-care tools like DMMH to be slim (i.e., ESM is not routinely used in clinical practice; Weermeijer et al., 2023a). By offering a free trial for the DMMH tool, we allow potential customers (e.g., practitioners) to get a feel for how ESM may help their clinical practice, determine if it meets their needs and fits with their clients, and decide if it is worth the cost. Additionally, it provides an opportunity for practitioners to get comfortable with the software and develop a sense of familiarity with the product.

A second promotion strategy is to invest in establishing our brand identity and improving our selling proposition. Currently, as identified in the SWOT analysis (cf. section 4.), our product was evaluated as lacking brand identity. Steps to improve this may include: rebranding to a memorable and simple brand name, creating a visual identity by using a consistent color palette in logos and/or website, establishing a clear mission and vision statement (a post market analysis example was included in section 0.1.), and including end-user testimonials in marketing campaigns. Similarly, it was evaluated that a clear selling proposition needs to be defined. Focusing on our goal of obtaining a medical device label could aid in formulating such a proposition.



A final promotion strategy concerns making use of government or organizational initiatives identified in our PESTEL analysis (cf. section 2.1.). For this, however, it will be crucial to establish relationships with politicians and/or prolific mHealth advocates.

6.3. Pricing

Based on the pricing of competitors, it appears a subscription-based fee is most applicable for the DMMH, regardless of who the cost is billed to (i.e., practitioners vs. clients). Similarly, a discounted annual subscription appears — as it is applied by most competitors (cf. section 5.) — as a successful marketing strategy. Given the competitive nature of the mHealth market for mental healthcare apps, we furthermore believe a competitive pricing strategy is most applicable. This includes continuously adapting the DMMH at a price similar as compared to other mental health tools that exist.

6.4. Distribution

A big opportunity for the DMMH, as also noted in the SWOT analysis (section 4), is to leverage the current relationships that exist within the project. Specifically, in our international multicentric cluster randomized clinical trial, we collaborate closely with mental health clinics and employed practitioners. These clinics, or individual practitioners working there, can act as a first point of entry when the DMMH is commercialized. Similarly, as they are familiar with using the tool, they may have increased willingness to use the DMMH.

Provided the DMMH software infrastructure is built following EU regulations, expansion towards North America should be feasible. Regulations are more lenient towards mHealth in North America, requiring little additional legal documentation. For example, in contrast to the EU¹⁰¹, it appears that the USA does not currently intend to enforce medical device regulation on mHealth products used to enhance psychiatric or psychological services¹⁰². Expanding to North America may, furthermore, be a priority as most mHealth revenue is made in this region (Cf. section 1.1.). Similarly, no additional translation work would be necessary as the DMMH is available in English. Strategic plans to expand to countries in Asia Pacific, with exception of Australia (i.e., similar regulatory framework as UK), are more problematic. For example, any company operating in China, both foreign and domestic, is required to allow insight from an investigating unit from the China Communist Party.



Provided the DMMH collects personal data, this could have a negative impact on brand reputation.

6.5. Customer relations

A first strategy to improve customer relations is to create an end-user advisory board. This advisory board would consist of practitioners and people making use of mental healthcare services. Together, these individuals can provide feedback and help co-create the templates and data visualizations the DMMH tool provides to practitioners to use with their clients.

A second strategy to engage with customers is to actively report practitioner and client testimonials. This can happen through social media channels such as twitter or LinkedIn. Additionally, it may be interesting to publish testimonials in magazines, blogs, or other media articles.

6.6. Further product development

The DMMH, as is, can serve as a tool for utilizing ESM in clinical practice. Yet, one particularly interesting future development may be to transform the IT infrastructure such that the DMMH is not only a tool for utilizing ESM, but also a full-fledged system for storing electronic patient health records (i.e., similar to QIT-online). Questionnaires for psychodiagnostics or routine outcome monitoring could, for example, be added with ease. Similarly, as the DMMH is developed in strict adherence to EU data safety regulations we have a qualitative reputation to leverage in negotiation with practitioners and private practices. One issue, however, is that our users are currently anonymously enrolled. Hence, for the DMMH to become an electronic patient record system, novel developments would be required that allow matching the anonymous user ID to a social security number (or similar). Similarly, additional features such as note-keeping or storing of recorded audio from a clinical session should perhaps be made possible.

The DMMH can be used as a tool to monitor mental health of employees or students in addition to it being a tool for clinical work. For this to work, however, we would need partnerships with clinical professionals willing to provide care to employees or students. Currently, such partnerships are not in place. Specifically, we are only testing the DMMH with practitioners working in clinics. For the DMMH to be used to assess the mental health of



employees or students, we would hence need to form partnerships with practitioners interested in providing such healthcare services to companies and/or universities. It is important to note that we do not envision every single employee or student making use of a service that includes a psychological assessment with a practitioner. Instead, we envision it as an optional service that employees or students can make use of out of their own accord, on the costs of the company — similar to Ginger or Calm for businesses (i.e., Sections 5.3 and 5.4).

Finally, and perhaps most important, concern the issue of copyrighting ESM templates that the DMMH tool provides. Currently, the templates are not copyrighted (cf. section 4.2) and can easily be stolen by competitors. Similarly, if copyright can be achieved it will be a difficult endeavour to monitor, and legally address, illegitimate use of our templates. However, provided that our project is coordinated by ESM experts with notable reputation and expert practitioners, one alternative may be to focus on leveraging their skill to offer valuable training programs and support to future practitioners interested in using DMMH-like tools. When such services are available, the product intrinsically gains value despite alternatives being available.



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