

Strengthening Primary Care with a Minimal Digital Ecosystem in Burkina Faso: Protocol for a Pragmatic Mixed-Methods Implementation Study

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Abstract

Background: In Burkina Faso, the Minimal Digital Ecosystem (MDE)—a suite of nine integrated digital tools—was introduced to support key health system functions, including care delivery, financial management, medication oversight, governance, and data use. However, evidence regarding the maturity of its real-world implementation and the determinants influencing its adoption remains scarce.

Objective: This pragmatic mixed-methods study aims to: (1) measure MDE implementation maturity across four dimensions (adoption, fidelity, penetration, sustainability); (2) identify multilevel determinants using the Consolidated Framework for Implementation Research (CFIR 2.0) and Normalization Process Theory (NPT); and (3) examine associations between implementation degree and primary health care (CSPS) performance

Methods: We employ a sequential explanatory design (QUAN?qual) in four districts covering 72 CSPS. Phase 1: Cross-sectional survey of all eligible health workers, facility managers, and community health workers (estimated n=612 respondents nested within facilities) using CFIR-and NPT-informed questionnaires. Following psychometric validation (exploratory/confirmatory factor analysis; reliability assessment via Cronbach's ? and McDonald's ?), we will fit multilevel models with CSPS random intercepts and district fixed effects to: (a) quantify between-facility implementation variance; (b) test associations with CFIR/NPT determinants; and (c) examine relationships with CSPS performance indicators. Phase 2: Purposive sampling of facilities with varying implementation profiles for interviews, focus groups, and observations, analyzed using reflexive thematic analysis to explain quantitative patterns

Results: Ethics approval was obtained from Burkina Faso's National Ethics Committee (No. 2023-06-136). Quantitative data

collection was completed in September 2025, and qualitative fieldwork is ongoing as of October 2025. Psychometric analyses are underway.

Conclusions: By addressing key evidence and measurement gaps in digital health implementation, this protocol will (i) generate context-specific guidance on implementing and institutionalizing a complex digital health ecosystem and (ii) provide validated, ready-to-use instruments to quantify implementation at the CSPS level. Together, these outputs will help policymakers and program managers define and track “implementation success,” informing—and accelerating—the scale-up and optimization of the MDE in resource-constrained settings.

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Original Manuscript

Strengthening Primary Care with a Minimal Digital Ecosystem in Burkina Faso: Protocol for a Pragmatic Mixed-Methods Implementation Study

ABSTRACT

Background: In Burkina Faso, the Minimal Digital Ecosystem (MDE)—a suite of nine integrated digital tools—was introduced to support key health system functions, including care delivery, financial management, medication oversight, governance, and data use. However, evidence regarding the maturity of its real-world implementation and the determinants influencing its adoption remains scarce.

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Keywords: implementation science; digital health; primary health care; Burkina Faso; CFIR; NPT; mixed methods; scale validation

INTRODUCTION

Modernizing health systems with digital technologies offers a practical path to tackle persistent primary health care (PHC) challenges across sub-Saharan Africa [1]. Adoption of digital innovations—from mobile health applications to electronic health records—is accelerating and has the potential to improve service delivery, data quality, and access to care, particularly for vulnerable populations [2,3]. However, fragmentation across digital tools can hinder strategic planning, monitoring and evaluation, and data-driven decision-making [4,5]. Real-world deployment also faces substantial barriers, including infrastructure gaps, limited digital literacy among healthcare workers, and resource constraints [6,7], which create a persistent gap between the promise of digital health and its system-level impact [6,7]. In Burkina Faso, where Primary Health and Social Promotion Centers [CSPS, Centres de Santé et de Promotion Sociale] forms the backbone of the health system [8], the Minimal Digital Ecosystem (MDE) was introduced to strengthen service delivery, health financing and financial management, medicines oversight, governance, and data use, while supporting the

national free-care policy (gratuité) [9]. The MDE is not a single application, but a set of integrated tools spanning point-of-care and managerial functions (e.g., electronic consultation registers, child and maternal care modules, individual electronic care records/FIS, free care management, stock and financial management, quality assessment, and community health platforms) [9]. Given this complexity, a rigorous evaluation of implementation is essential to understand determinants of success and to guide sustainability and scale-up.

This study addresses two critical gaps in the research on digital health implementation. First, validated, standardized instruments to measure the maturity of complex digital health ecosystems in resource-constrained settings remain scarce [10,11]. While frameworks such as the Consolidated Framework for Implementation Research (CFIR) and Normalization Process Theory (NPT) enumerate potential determinants, few tools enable their quantification and examination alongside key implementation outcomes (adoption, fidelity, penetration, sustainability) [10,12]. Second, this measurement gap creates a translational challenge: without evidence-based benchmarks, policymakers cannot define “implementation success” to target support or guide scaling decisions. In Burkina Faso, the widespread, non-random rollout of the MDE precluded a traditional quasi-experimental design but created a pragmatic opportunity to answer a stakeholder question from the Ministry of Health: *At what threshold can a PHC facility be considered to have fully implemented the MDE?* This underscores the need for an evidence-based, measurable definition of “implementation success” to inform resource allocation and policy [10]. Using a pragmatic, mixed-methods design [13], this protocol aims to generate a contextualized understanding of MDE implementation, identify levers for optimization, and produce validated instruments to assess implementation maturity—evidence intended to inform digital health policy in Burkina Faso and similar resource-constrained settings.

Study goals and objectives

The MDE evaluation was initially structured into five complementary surveys across its implementation stages [9]. The initial phase profiled users analyzed the implementation, and evaluated the early effects; the second explored the deployment context, including resources, preparedness, user perceptions, and the free access application; and the third assessed deployment levels, utilization, satisfaction, service governance, and quality. While this multi-phase approach provided foundational data, the objectives for the ongoing fourth survey and the prospective fifth were substantively revised in response to real-world implementation challenges that necessitated a shift in the evaluation's focus.

Defining the "Pragmatic" Approach

We have adopted a pragmatic paradigm[14], an approach in implementation science that prioritizes useful, real-world solutions over theoretical purity. We aim to generate actionable knowledge in the complex setting of actual practice, not to test a hypothesis under perfect, controlled conditions. Our approach is pragmatic in three specific ways:

First, from a methodological standpoint, we embrace flexibility in response to field realities. When intervention contamination threatened the validity of our original quasi-experimental design, we pivoted to an implementation-focused evaluation better suited to the real-world context.

Second, from an epistemological standpoint, we integrate multiple frameworks (CFIR 2.0, NPT) and methods (quantitative surveys, qualitative inquiry). We recognize that no single approach can adequately answer the complex questions our stakeholders have.

Third, contextually, we are evaluating the MDE "as deployed" rather than under idealized conditions. We treat the natural variation in implementation not as statistical 'noise' to be controlled, but as a rich source of insight into what is actually happening on the ground.

This pragmatic orientation ensures our findings will be directly relevant to policymakers and program managers who are navigating the complexities of scaling up digital health in resource-constrained settings.

Justification for the revised evaluation objectives

Initially, our evaluation plan for the MDE was a quasi-experimental design. We intended to compare two intervention districts (Ténado and Ziniaré) with two control districts (Manga and Sapouy) to assess the ecosystem's impact. However, the operational reality of field deployment necessitated a significant deviation from this a priori approach.

However, a key challenge emerged early on: the MDE tools began to progressively and non-randomly diffuse into our designated control districts. This "contamination" effect fundamentally compromised our original quasi-experimental design—a common problem in real-world implementation studies.

As a result, a robust, direct comparison between the groups became untenable, making it impossible to isolate the MDE's specific effects. This cross-contamination severely threatened the study's internal validity; we could no longer confidently attribute observed outcomes to the intervention and faced a high risk of biased or artificially weakened (attenuated) effect sizes.

Consequently, we have reoriented the evaluation focus. Rather than pursuing a simple effectiveness question, our approach now aligns more closely with an implementation science perspective, which acknowledges and addresses the complexities of real-world contexts [14].

This real-world deployment scenario has raised a critical question from Ministry of Health stakeholders: at what threshold of adoption and routine use can a health facility be considered to have fully implemented the MDE initiative? This new question aligns perfectly with the field's focus on understanding and measuring implementation outcomes—the direct effects of actions taken to implement an innovation, which serve as key indicators of success [10].

To address both the contamination challenge and this new, emergent research question, we have adapted our methodology. Instead of a rigid comparative analysis, we are now using a pragmatic, integrated evaluation design. This approach, similar to a Type 1 hybrid effectiveness-implementation design, enables us not only to test the intervention but also to gather rich data on the implementation context simultaneously. This shift ensures our evaluation remains relevant and provides actionable insights for future scale-up [15].

Our revised focus will assess the varying levels of MDE tool adoption (or "dose"), its integration into clinical and management workflows, and the maturity of its use across all districts. We will adjust our analytical approach to explore the relationship between these implementation outcomes and health service outcomes [10]. This will allow us to better understand the impact of the mechanisms, even in the context of widespread tool availability.

Ultimately, this approach will provide stakeholders with more nuanced and actionable insights on how to optimize MDE implementation for greater impact on the health system.

Specifically, this study aims to:

- Assess the maturity of MDE implementation. We will evaluate the level of adoption, fidelity to its intended use, penetration into existing practices, perceived sustainability, and institutionalization of its various tools. We will use the Normalisation Process Theory (NPT) framework to guide our understanding of institutionalization.
- Identify multi-level determinants. We will utilize the Consolidated Framework for Implementation Research (CFIR) 2.0 to identify the facilitators and barriers that influence the degree and quality of MDE implementation. This will encompass a broad range of factors, including intervention characteristics, outer and inner settings, individual user characteristics, and the implementation process itself.
- Evaluate the association between MDE implementation and health facility outcomes. We will assess the relationship between the degree of MDE implementation and the readiness and quality of health facility services. This evaluation will particularly focus on key areas such as service delivery, financial and medication management, the efficiency of free healthcare provision, and the use of data for decision-making

Hypotheses

Building on the study's objectives to evaluate the implementation and effects of the MDE, we propose the following hypotheses to guide our investigation:

1. **H1: Implementation Maturity Variance.** We hypothesize that the maturity of MDE implementation will vary significantly across different MDE tools, Primary Health and Social Promotion Centers (CSPS), and the districts. This reflects the complexity of real-world implementation contexts.
2. **H2: Multi-Level Determinants.** We hypothesize that the degree and quality of MDE implementation are associated with multi-level determinants. Specifically, positive factors at the inner setting level (e.g., engaged leadership, adequate resources, a favourable implementation climate) and within the implementation process (e.g., quality of training, ongoing support) will be positively correlated with a higher degree and better quality of MDE implementation.
3. **H3: User Perceptions and Adoption.** We hypothesize that the degree of MDE implementation is associated with user perceptions of the intervention's characteristics. A positive perception of MDE characteristics (e.g., relative advantage, low complexity) by individual users will be positively correlated with higher adoption and utilization rates of MDE tools, contributing to a greater overall degree of implementation.
4. **H4: Implementation and Facility Outcomes.** We hypothesize that a higher degree of MDE implementation will be positively associated with improved health facility readiness and performance. This association will be particularly evident in enhanced service delivery, more efficient financial and medication management, better management of free healthcare services, and increased utilization of data for informed decision-making within CSPS.

METHODS

Study Setting

This study is being conducted in four health districts in Burkina Faso: Ziniaré (Plateau Central region), Ténado and Sapouy (Centre-Ouest region), and Manga (Centre-Sud region). While these districts were initially selected for a quasi-experimental design [16], the widespread, real-world deployment of the MDE has reframed the study. This collection of districts now serves as a valuable natural experiment [17], allowing us to assess varying levels of MDE implementation and identify the multi-level determinants influencing its adoption and institutionalization across diverse settings.

The MDE in Context: Novelty and Distinctiveness

The MDE represents a novel approach to digital health implementation in sub-Saharan Africa. Unlike standalone digital interventions, such as isolated electronic medical record systems or single-purpose mobile health applications, the MDE deliberately tries to integrate nine complementary tools into a cohesive ecosystem spanning clinical care, supply chain management, financial tracking, quality assurance, and community health [9]. The "minimal" designation reflects a strategic choice: rather than implementing a comprehensive, resource-intensive hospital information system, Burkina Faso's Ministry of Health prioritized essential, interoperable tools deployable at the PHC level with existing infrastructure[9]. This ecosystem model has not been systematically evaluated elsewhere in SSA, making this study among the first to rigorously assess the implementation of an integrated digital health suite—as opposed to discrete applications—in a low-resource setting. Additionally, while Burkina Faso has previously piloted individual digital health tools (e.g., DHIS2 for health information, isolated mHealth interventions), the MDE's distinguishing feature is the intentional harmonization and co-deployment of multiple tools, designed to generate synergies in data flow, reduce parallel workflows, and support holistic PHC strengthening[9].

Table 1. Key Characteristics of the Selected Study Districts in Burkina Faso.

Characteristic	Ziniaré	Ténado	Manga	Sapouy
<i>Administrative Region</i>	<i>Plateau-Central</i>	<i>Centre-Ouest</i>	<i>Centre-Sud</i>	<i>Centre-Ouest</i>
Classification	Peri-urban	Rural	Peri-urban	Rural
Total Population	345,471	211,543	340,912	267,015
Number of Health Facilities	72	28	48	33
<i>Key Health Indicators</i>				
Facility-based Delivery Rate (%) ¹	102.2	95.6	111.3	103.6
ANC4 Visit Rate (%)	52.7	65.4	51.5	30.3
IPTp3 Rate (%)	73.9	70.1	70.4	54.7
Neonatal Mortality Rate (per 1,000)	2.3	1	14	6
Maternal Mortality Ratio (per 100,000)	14.5	0,0	25	51.8

Source: 2023 Statistical Yearbook of the Ministry of Health

¹Rates above 100% Facility-based Delivery may be due to using projected population denominators or to the inflow of patients from other districts.

The inclusion of all four districts enables the study to leverage their distinct characteristics—such as urban/rural profiles, population density, and pre-existing digital infrastructure—to robustly address the implementation-focused research objectives. This ensures a comprehensive evaluation that considers a broad range of contexts.

Intervention Description

The intervention under evaluation is the Minimal Digital Ecosystem (MDE), a suite of integrated digital tools designed to strengthen primary healthcare in the four study districts of Burkina Faso. The MDE aims to enhance operational efficiency, service quality, governance, and data-driven decision-making by harmonizing various digital applications into a cohesive system. The core tools of the MDE are detailed in Table 1.

Table 1. Summary of Digital Health Tools: Purpose, Users, and Technology Platforms

Tool Name	Core Function & Purpose	Primary Users & Technology
REC-PCIME	Guides child health consultations using the IMCI protocol; creates electronic patient records.	Health Workers (Tablet; CommCare)
REC-Maternité	Guides maternal & newborn care (ANC, delivery, PNC, family planning); creates electronic records.	Health Workers (Tablet; CommCare)
E-Flux Financier	Monitors real-time financial data (income, expenditure) and automates facility financial reports.	Financial Managers (Tablet)
FIS (E-Care Sheet)	Digitizes patient care sheets for the national free healthcare (gratuité) program; serves as a claim form.	Health Workers (Tablet)
NetSIGL 2.0	Manages real-time data on medicine and supply stocks across the health system.	Health Workers (Tablet; DHIS2)
eSanteCoM	Provides community-level diagnostic and treatment guidelines, and data collection for community health workers (ASBCs).	ASBCs (Phone; CommCare)
E-Qualite	Manages digital checklists for internal/external quality audits and facility certification processes.	Facility Managers (Tablet/Computer; DHIS2)
E-Gratuité	Collects and monitors data for the national gratuité scheme, including invoicing, payments, and workload, Follow-up/oversight of medical devices and equipment.	Facility & District Managers (Tablet/Computer; DHIS2)
Dashboard	Visualizes and integrates key performance indicators from all MDE tools to support decision-making.	Health Managers at all levels (Computer/Browser)

Note: A detailed description of each tool, including its functionalities, delivery mode, and implementation strategies, is provided in the supplementary materials. These descriptions are structured according to the TIDieR (Template for Intervention Description and Replication) checklist to ensure a complete and standardized characterization.

MDE intervention theory of change

The MDE's Theory of Change posits that core health system functions will be digitized and streamlined by deploying an integrated suite of digital tools and supporting their use through targeted training. This is expected to improve clinical protocol adherence, financial and supply chain efficiency, and systematic data collection at the facility and community levels. By aggregating this newly captured, real-time data into a central dashboard, the MDE then aims to foster evidence-based decision-making among managers. The ultimate goal of this combined improvement in service quality, operational efficiency, governance and data utilization is to produce a modernized

and strengthened primary healthcare system capable of delivering higher-quality and more equitable care.

Study Design

This study will employ a sequential explanatory mixed-methods design [18], guided by a pragmatic approach [14]. This design is particularly well-suited to our revised objectives, as it allows us to pivot from a rigid comparative analysis to an observational one, an ordinary and necessary adjustment when researchers cannot fully control interventions in real-world settings [19]. The design will be implemented in two distinct phases, where the quantitative findings inform the subsequent qualitative inquiry.

Phase 1: Quantitative (QUAN)

The first phase of the study will consist of a cross-sectional quantitative survey designed to address both the primary and secondary objectives. This phase will assess the extent of MDE implementation across all participating health facilities and districts. To achieve this, we will quantify key implementation outcomes based on the Consolidated Framework for Implementation Research (CFIR), with a specific focus on adoption, fidelity, penetration, and sustainability. The findings will support the development of a typology of implementation profiles, which will inform and guide the strategic deployment of a digital health ecosystem in Burkina Faso.

We will estimate the associations between the implementation level and (1) multilevel determinants specified by CFIR 2.0 and Normalization Process Theory (NPT), and (2) key health facility performance indicators, using appropriate multivariable models.

This phase will answer the "what" and "how much" questions, providing a broad overview of implementation maturity and identifying the significant relationships outlined in our hypotheses (H1-H4).

Phase 2: Qualitative (QUAL)

The second phase will consist of a qualitative inquiry designed to explain and elaborate upon the findings from the quantitative phase. Using a multiple-case study approach, we will purposively select a subset of health facilities that demonstrate particularly high, low, or mixed levels of implementation, based on the quantitative results. This phase will explore the "how" and "why" behind the statistical patterns through semi-structured interviews, focus groups, and direct observation. For example, it will help us understand why specific MDE tools are well-integrated while others are not, how specific facilitators (e.g., leadership engagement) operate in practice, and what contextual barriers hinder the translation of the MDE into improved performance.

Theoretical frameworks

Consolidated Framework for Implementation Research (CFIR 2.0)

We will primarily use CFIR 2.0 to assess the extent of MDE implementation and its determinants [12]. CFIR 2.0 provides a structured approach by categorizing determinants into five key domains: intervention, outer setting, inner setting, individuals, and process. Crucially, its Outcomes Addendum links these implementation processes to their results, addressing a key need in the field [12]. This is particularly relevant, as it directly links these implementation processes to their results, a critical need in the field. We will use this framework to analyze CFIR-defined contextual factors as potential moderators of the MDE's degree of implementation. The strength of CFIR 2.0 lies in its ability to concurrently evaluate the degree of implementation and its determinants, which helps to clarify the relationships between them [12].

Normalization Process Theory (NPT)

Complementarily, we will use NPT [20] to analyze how MDE tools are integrated and institutionalized into daily practices. NPT focuses on the collective work required for a new practice

to become routine, examining it through four key constructs: coherence, cognitive participation, collective action, and reflexive monitoring [20]. NPT's specific relevance to our evaluation is its ability to provide a nuanced understanding of how MDE tools become—or fail to become—normalized and sustained within the complex daily workflows of healthcare providers. While CFIR helps identify what factors influence implementation, NPT will illuminate the social dynamics and processes that embed these tools into routine practice. Applying NPT will enable a precise analysis of the mechanisms driving the integration and institutionalization of MDE tools by examining collective sense-making, user engagement, practical operationalization, and iterative appraisal and adaptation processes [20].

Population and Selection Criteria

Recruitment and Sampling Procedures

Quantitative Phase: Sample Size Justification and Composition

This study will engage a multi-level population across the four health districts. We selected 72 primary health centers (PHCs; $J=72$) across four districts and will conduct a census of all eligible cadres within each facility (healthcare providers, facility managers (ICPs or chief doctors), Pharmaceutical Depot Managers, facility management committee treasurers, and community health workers (ASBCs). Based on comprehensive staffing audits conducted during study preparation, the sample composition is detailed in Table 2.

Table 2. Sample Composition by District and Cadre

District	No. of CSPS	ICPs	Providers ¹	Depot Managers	Treasurers	ASBCs ²	Total per District
Ziniaré	20	20	60	20	20	60	180
Manga	20	20	60	20	20	60	180
Ténado	16	16	48	16	16	40	136
Sapouy	16	16	48	16	16	40	136
Total	72	72	216	72	72	200	612

¹Providers include nurses, midwives, and other clinical cadres using MDE tools; estimated at 3 per facility on average based on staffing data.

²ASBCs (Community-Based Health Workers) average 2.5-3 per facility catchment area; counts reflect active ASBCs trained on eSanteCoM.

This configuration yields a total expected sample of $n=612$ respondents (range: 585-640 depending on ASBC availability and staff turnover). The sample size was determined through the following considerations:

1. Precision for Implementation Scores

With $n=612$, the margin of error for the primary continuous implementation score (assuming $\sigma=1.0$ on a standardized scale) is ± 0.08 at 95% confidence—sufficient precision for characterizing implementation maturity and detecting meaningful facility-level variation.

2. Multilevel Modelling Requirements

The nested design (respondents within CSPS within districts) requires adequate sample sizes at each level:

Level 1 (Individual): $n=612$ provides ample power for individual-level predictors. **Level 2 (CSPS):** $J=72$ facilities substantially exceed the minimum recommended threshold of 50 clusters for stable variance component estimation [21]. **Level 3 (District):** With only 4 districts, we will model the district as a fixed effect rather than a random effect, avoiding the instability associated with <10 clusters [22,23].

The mean cluster size of $m \approx 8.5$ respondents per facility creates a design effect of $DEFF=1+(m-1) \times ICC$. Under plausible ICC values informed by prior implementation research in SSA settings ($ICC=0.05$ to 0.20), the effective sample size remains adequate: $ICC=0.05 \rightarrow DEFF=1.375 \rightarrow n_{eff}$

= 445; ICC=0.10 → DEFF=1.75 → n_{eff} = 350; ICC=0.20 → DEFF=2.50 → n_{eff} = 245. All scenarios provide sufficient power for multilevel regression analyses.

3. Power for Primary Hypotheses.

Power analyses were conducted using Optimal Design Plus software[24], assuming: Primary outcome: standardized implementation score (mean=0, SD=1); Two-level model (individuals nested in facilities); Target power: 80% at $\alpha=0.05$ (two-tailed); Anticipated ICC: 0.10 (conservative estimate based on similar digital health implementation studies).

Results indicate adequate power (>80%) to detect: a) Small-to-medium associations ($r \geq 0.15$) between individual-level determinants and implementation scores, b) Medium facility-level effects (Cohen's $d \geq 0.40$) when comparing facilities by key characteristics (e.g., urban/rural, high/low leadership engagement), c) District differences of $d \geq 0.50$ using fixed-effects contrasts

4. Facility-Level Predictor Capacity

With $J=72$ facilities and 4 districts, we can reliably estimate up to 28-30 facility-level predictors (following the guideline of at least 2.5 clusters per predictor) [21]. Our analysis plan includes approximately 12-15 facility-level covariates derived from CFIR domains (e.g., organizational readiness, resource availability, leadership engagement), well within this limit.

5. Accounting for Attrition

We anticipate 8-10% non-response due to extended leave, turnover, or refusal. Our target of 612 eligible respondents includes a 10% buffer, ensuring a minimum analyzable sample of $n \approx 550$.

Qualitative Phase: Purposive Sampling Strategy

Following quantitative analysis, we will employ maximum variation sampling to select facilities representing the full implementation spectrum. Target qualitative sample sizes, informed by prior implementation research and saturation principles [25–27]:

Semi-structured interviews. Semi-structured interviews will be conducted with 24-30 participants carefully selected to represent multiple levels of the health system and community stakeholders. This will include 12-15 facility staff such as infection control and prevention personnel, healthcare providers, and depot managers drawn from 8-10 purposively selected primary health centers. Additionally, 8-10 key informants operating at the district, regional, and central levels will be interviewed, including members of Essential Childhood Disease committees and Medical Device Equipment focal points. Finally, 4-5 community representatives will participate, comprising community-based health worker supervisors and members of health facility management committees, ensuring that community perspectives are adequately captured in the data collection process.

Focus group discussions: Focus group discussions will be organized into 6-8 groups, with each group comprising 6-8 participants to facilitate in-depth collective dialogue and exchange of perspectives. The composition will include 2-3 provider groups that will be stratified according to their level of implementation experience to capture varied insights based on operational context. Two focus groups will be conducted with community-based health workers to understand frontline service delivery challenges and experiences. Additionally, 1-2 facility management groups will be convened to explore organizational and administrative perspectives on program implementation. Finally, one focus group will bring together district managers to examine coordination, supervision, and support mechanisms at the district level, ensuring comprehensive representation across different stakeholder categories within the health system.

Recruitment will continue until thematic saturation—the point at which no substantively new codes or themes emerge across two consecutive interviews or FGDs[26]. We anticipate saturation within the planned sample range based on the study's focused scope and homogeneous professional populations.

Outcomes and Data Collection

The study's primary and secondary outcomes are defined and measured as follows:

Primary Outcomes

a) Degree of Implementation of MDE tools

This outcome will be assessed across four key dimensions, aligned with implementation science frameworks (CFIR 2.0), including:

- **Adoption:** This dimension will be assessed by examining the tools' perceived usefulness and ease of learning, alongside their initial utilization rate.
- **Fidelity:** This will be measured by evaluating the adherence to intended procedures and the completeness of data entered.
- **Penetration:** This dimension will quantify the percentage of eligible activities covered by the tool and its integration into daily routines.
- **Sustainability:** This will encompass the intention to continue use, the perception of the tool as standard practice, and the availability of ongoing support.

These dimensions will be measured using questionnaires tailored to each MDE tool, employing Likert scales, multiple-choice questions, and percentage estimates.

b) Implementation Score Calculation

To operationalize the degree of implementation, a multi-step scoring methodology will be applied [28,29]. First, in terms of data coding, responses from Likert scale items will be numerically coded (for "Strongly Disagree" to 5 for "Strongly Agree"). Any negatively worded items will be reverse-coded so that higher scores consistently indicate more positive implementation outcomes.

An overall implementation score will be calculated for each MDE tool in a two-step process: (a) the mean score for all items within each of the four dimensions (Adoption, Fidelity, Penetration, Sustainability) will be calculated; (b) these four dimension scores will then be averaged to generate a single, overall implementation score for that tool [10,12].

Finally, to create a composite score for the entire MDE, the mean of the individual tool scores will be calculated. A weighted average, where tools are assigned weights based on strategic importance, will also be explored as an alternative analytical approach to provide a more nuanced overall score. The tool-weighting exercise will be conducted with stakeholders (central Ministry of Health decision-makers, tool developers, and district/facility managers) using established approaches for participatory, multi-criteria weighting [30–32]. All scale construction and scoring will follow good practice in measurement and psychometrics [33].

c) Determinants of Implementation

These factors will be identified and assessed using the five domains of the Consolidated Framework for Implementation Research (CFIR 2.0): Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and the Implementation Process. They will be measured primarily by the questionnaire administered to health center managers (ICPs) and through open-ended questions in the tool-specific questionnaires and the qualitative data.

d) Secondary Outcomes

- The level of institutionalization will be measured using constructs from Normalization Process Theory (NPT), primarily via the "Sustainability" sections of the questionnaires and explored in-depth through qualitative data.
- The perceived impact of the MDE on quality of care, efficiency, governance and user satisfaction will be explored qualitatively and via specific questions in the health center

manager questionnaire

Measurement Instruments

Data for this study will be collected using a suite of mixed-methods instruments designed to capture both the degree of MDE implementation and its underlying determinants.

Quantitative Instruments

Two primary structured questionnaires will be used for the quantitative phase:

- For tool-specific implementation, a set of modular questionnaires will be administered to the direct users of each MDE tools (e.g., REC-PCIME, NetSIGL). Each module is tailored to a specific tool and is designed to measure the primary implementation outcomes (Adoption, Fidelity, Penetration, Sustainability) using a combination of Likert scale items, multiple-choice questions, and direct estimates.
- For the determinants of implementation, a second questionnaire, guided by the CFIR 2.0, will be administered to all facility managers (Infirmiers Chefs de Poste - ICPs) and a sample of CBHW. This instrument assesses the multi-level determinants influencing implementation, such as organizational readiness, leadership engagement, and resource availability.

Qualitative Instruments

Semi-structured interviews and focus group discussion guides will be developed for the qualitative phase. The CFIR and NPT will theoretically inform these guides. Critically, the guides will be finalized after the initial analysis of the quantitative data to ensure they specifically explore and explain key statistical findings, such as implementation challenges, performance variations between sites, or unexpected results.

Scale Development and Validation

Prior to the main data analysis, a rigorous process will be undertaken to develop and validate the quantitative measurement scales from the questionnaire data[34]. This process applies to the composite implementation scores for each MDE tool and for the MDE overall, as well as to scales measuring key implementation determinants (e.g., constructs from the CFIR framework).

- We will evaluate measurement properties in line with COSMIN guidance, covering content validity, structural validity, internal consistency, reliability, measurement error, and hypothesis-testing construct validity. Content validity was addressed through expert review and piloting (relevance, comprehensiveness, comprehensibility) [35]. For structural validity, we will first assess sampling adequacy ($KMO \geq 0.70$; Bartlett's test $p < .001$) and conduct EFA using polychoric correlations with minimum residual extraction and oblique rotation; item retention requires primary loading ≥ 0.40 , cross-loading difference ≥ 0.30 , and communality ≥ 0.30 . We will then run CFA using WLSMV for ordinal Likert items (or ML/MLR if distributions are approximately continuous), reporting fit indices with a priori thresholds CFI/TLI ≥ 0.90 (preferably ≥ 0.95), RMSEA ≤ 0.08 (preferably ≤ 0.06), and SRMR ≤ 0.08 ; models failing these will be revised only based on theory and pre-specified modification rules [36]. Internal consistency will be summarized using Cronbach's α and McDonald's ω , targeting α and ω values of 0.70 or higher for newly adapted scales and 0.80 or higher where feasible [28]. For multidimensional scales, α/ω will be reported per subscale; when a bifactor structure is indicated, we will report ω_H (omega hierarchical).
- Only scales demonstrating satisfactory psychometric properties (i.e., strong validity and reliability) will be retained for subsequent hypothesis testing and regression analyses.

Data Collection

Data collection will take place over one month. Quantitative data (in the form of questionnaires) will be collected first, followed by qualitative data (including interviews, focus groups, and observations). System usage data (logs) will be collected retrospectively and prospectively during the study period.

Data Management

Quantitative data will be collected electronically using the Open Data Kit (ODK) platform, with forms programmed to include quality controls such as skip logic, input validation, and required fields. Encrypted data will be submitted daily to a secure central server. Qualitative audio recordings will be transcribed verbatim and fully anonymized by replacing personal identifiers with unique codes. All study data will be stored on a secure, password-protected server with access restricted to the research team and will be securely archived after the study, in accordance with relevant ethical guidelines.

Implementation Feasibility and Mitigation Measures

We anticipated and proactively managed typical field constraints. To address geographic barriers across 72 often-remote facilities, data collection was scheduled before the rainy season, local enumerators were recruited, and contingency transport plans were prepared. Respondent availability was improved through pre-arranged appointments during low-volume periods and multi-day visits at busier sites. Technology limitations were mitigated with offline-enabled forms, portable chargers, and standardized backup procedures. To minimize attrition, we used a census approach and engaged stakeholders throughout, yielding a 94.3% response rate. Qualitative saturation will be monitored in real time by two researchers conducting concurrent analysis, with flexible recruitment to target emerging gaps. Risks of social desirability bias are reduced through neutral-questioning training, use of external data collectors, and triangulation with system usage logs and observational notes. Timeline feasibility is supported by deploying 32 enumerators concurrently over 4 weeks with strong district-level coordination. Finally, coding reliability will be ensured through dual independent coding of 25% of transcripts, followed by consensus meetings to reconcile discrepancies and balance analytic rigor with interpretive depth.

Statistical Analysis Plan

Quantitative Analysis

The statistical analysis will be conducted using Stata software (version 19). All hypothesis tests will be two-tailed, with the significance level (α) set at .05. The analysis will commence only after the successful psychometric validation of all measurement scales.

Data Preparation and Cleaning

Before analysis, we will conduct rigorous data preparation. We will assess the extent and patterns of missingness; if missing data are minimal (<5%) and consistent with missing completely at random (MCAR), we may use listwise or pairwise deletion for specific analyses. For more substantial or systematic missingness, we will apply multiple imputation to generate analysis-ready datasets for regression modeling. We will screen for univariate outliers (e.g., via boxplots) and inspect bivariate relationships using scatterplots; influential observations will be reviewed and addressed case by case. Finally, we will evaluate distributional assumptions for all continuous variables (e.g., implementation scores) using visual diagnostics (histograms, Q-Q plots) and formal tests (e.g., Shapiro-Wilk).

Descriptive Analysis

A comprehensive descriptive analysis will be conducted to summarize the sample and key variables: First, the demographic and professional characteristics of the participants and health facilities will be summarized using frequencies and percentages. Secondly, the implementation scores for each MDE tool and the overall composite score will be summarized using key descriptive statistics, including the mean, standard deviation, median, interquartile range (IQR), and range. Finally, the determinant scores, derived from the scales measuring the CFIR constructs, will be summarized using descriptive statistics.

Inferential Analysis Plan

The inferential analysis will be structured to test the study's hypotheses systematically.

A series of comparative tests will be conducted to test for variation in implementation (H1). Depending on data distribution, Student's t-tests or Mann-Whitney U tests will compare scores between two groups (e.g., urban vs. rural). In contrast, ANOVA or Kruskal-Wallis tests will compare scores across the four districts.

To explore associations with determinants (H2 & H3), Pearson's correlation coefficients (for linear relationships) or Spearman's correlation coefficients (for monotonic relationships) will be calculated to assess the strength and direction of the association between implementation scores and various determinant scores.

Given the hierarchical structure of the data—with health workers nested within health facilities (CSPS), which are nested within districts—linear mixed-effects models (multilevel models) will be the primary analytical strategy to address H4 and overall heterogeneity. This approach correctly accounts for the non-independence of observations and allows for variance partitioning across levels [37–39].

The modelling will proceed sequentially:

- **Step 1:** An initial model with no predictors - Unconditional (Null) Model will be fitted to the main implementation outcome. This model will decompose the total variance into its components at the individual, facility, and district levels. The Intraclass Correlation Coefficient (ICC) will be calculated to quantify the proportion of total variance in MDE implementation attributable to clustering at the facility and district levels. This directly measures the heterogeneity of implementation across contexts.
- **Step 2:** Subsequently, a full multilevel model will be constructed by adding predictors at the individual level (e.g., user age, professional experience, perceptions of the MDE), the facility level (e.g., CSPS size, resource availability, leadership engagement), and the district level (e.g., contextual factors).
- **Step 3:** This final model will allow us to identify the individual, facility, and contextual determinants significantly associated with the degree of MDE implementation while appropriately controlling for the nested data structure. It will also reveal how much of the variation in implementation is explained by facility-related factors versus broader contextual factors.

Model Diagnostics

The final regression models will be rigorously checked for adherence to statistical assumptions, including linearity, normality of residuals, homoscedasticity, and the absence of significant multicollinearity (assessed using the variance inflation factor, or VIF).

Qualitative Analysis:

Overall approach and rationale

The qualitative component of this study will be guided by a reflexive thematic analysis approach, following the six-phase process described by Braun and Clarke [40,41]. This methodology was chosen for its flexibility and rigor in identifying, analyzing, and reporting patterns (or themes) within the data. It is particularly well-suited for exploring the complex, multi-level phenomena associated with the implementation of the MDE, allowing for a rich, detailed, and nuanced understanding of the "how" and "why" behind the quantitative findings.

Data preparation

All audio recordings from semi-structured interviews and focus group discussions will be transcribed verbatim. The transcripts will then be de-identified and anonymized to protect participant confidentiality; all personal names or unique identifiers will be replaced with alphanumeric codes. These anonymized transcripts, field observation notes, and open-ended survey responses will form the complete dataset for analysis. Coding and Thematic Development Process

The analysis will be conducted using CAQDAS software (e.g., NVivo) [42] and will follow a systematic, six-phase thematic process. A hybrid coding strategy will be employed, combining a deductive approach guided by our theoretical frameworks (CFIR 2.0 and NPT) with an inductive, data-driven approach to identify emergent themes [43].

Strategies for Ensuring Analytical Rigor and Trustworthiness

To ensure analytical rigor, we will implement several key strategies. These include triangulation across different data sources and methods, regular peer debriefing to enhance the coding and interpretation's credibility, thick description supported by participant quotations in the final report, and analyst reflexivity maintained through a detailed journal.

Mixed-Methods Integration

In line with this study's sequential explanatory design (QUAN → qual)[18], the quantitative and qualitative strands will be integrated at multiple points. First, the quantitative results will directly inform the qualitative phase by guiding the purposive sampling of cases (e.g., high- and low-performing sites) and the development of tailored interview and focus group guides. At the final interpretation stage, both datasets will be synthesized to generate meta-inferences[44]. Qualitative data will be used to explain and contextualize quantitative statistical patterns, while triangulation across the two strands will serve to confirm findings and strengthen the overall validity of the study's conclusions [45].

Consent to Participate

Prior to participation, all individuals provided informed consent, either written or, for non-literate participants, witnessed verbal, consent, after being fully informed of the study's objectives, their right to withdraw, and all confidentiality measures.

Ethical Considerations

This study received full ethical approval from the National Ethics Committee for Health Research of Burkina Faso (Approval No. 2023-06-136) and obtained additional authorizations from the Ministry of Health and relevant district authorities. Data will be immediately anonymized using unique codes to ensure confidentiality, stored on secure, password-protected servers with restricted access, and all consent forms will be stored separately. No financial compensation was provided; however, travel costs for focus group participants were reimbursed. Additionally, no personal identifiable information will be used in any publications.

Harms and Safety Monitoring

Given the minimal-risk, non-clinical nature of this study, a formal Data and Safety Monitoring Board (DSMB) has not been constituted. Any unexpected adverse events or breaches of confidentiality will be reported to the Ethics Committee for Health Research (ECHR) in accordance with national regulations.

RESULTS

As of October 2025, qualitative data collection is in progress and quantitative analyses have commenced. Quantitative work currently includes data cleaning and preparation, descriptive summaries of participant and facility characteristics, and psychometric evaluation of all study scales (item performance, internal consistency, and construct validity). Multilevel modelling and qualitative thematic analysis are planned and will be initiated as data preparation milestones are met. Analytical activities are expected to conclude by November 2025. No outcome data are reported here, as this is a protocol. Finalized implementation scores and all model- and theme-level findings will be disseminated in the final study report and subsequent publications. Ethics approvals

and consent procedures were completed before data collection, as detailed in the Methods section.

Expected Outcomes

This study will produce two categories of outcomes: (1) empirical findings on the maturity and determinants of Minimal Digital Ecosystem (MDE) implementation, and (2) methodological products—validated, ready-to-use measurement scales and scoring procedures.

Empirical findings

This study will generate a nuanced portrait of implementation maturity across primary health care (PHC) facilities and districts, capturing adoption, fidelity, penetration, and perceived sustainability, while quantifying between-facility heterogeneity through multilevel models (including intraclass correlation coefficients and random-intercept variance). It will further produce an evidence map of multilevel determinants, anchored in CFIR 2.0 domains and complemented by NPT-informed patterns of normalization, integrating quantitative estimates with qualitative explanations. We will also document the extent to which MDE tools are institutionalized and routinely used within clinical and managerial workflows, and examine their associations with PHC readiness and performance indicators (service delivery, stockouts, financial reporting, and data use). Together, these findings will culminate in actionable, context-specific recommendations to optimize and scale the MDE tailored to district and facility conditions.

Methodological products: implementation measurement scales

This study will develop a suite of validated scales to quantify implementation outcomes for each MDE tool and for the ecosystem as a whole, following COSMIN guidelines (content and structural validity, reliability, measurement error, and hypothesis-testing construct validity). For each scale, we will report full psychometric evidence, including EFA/CFA results with model fit indices and item loadings, internal consistency (α and ω), and ω_H where a bifactor structure is indicated—alongside measurement invariance checks across districts and staff cadres. Building on these metrics, we will construct a composite MDE implementation index with alternative weighting schemes (equal vs. policy-informed weights), accompanied by prespecified sensitivity analyses. To facilitate uptake and reuse, user materials will be packaged for dissemination: finalized instruments with item wording, a scoring codebook, and worked examples of score calculation, all provided as Multimedia Appendices for routine monitoring and future studies.

Collectively, these outputs will enable policymakers and program managers to define, measure, and track “implementation success” using transparent, psychometrically sound tools. The empirical findings will guide the prioritization of supports (training, supervision, infrastructure) to accelerate the effective scale-up of the MDE.

Expected Contributions of the Study

This study will advance implementation science for complex digital health interventions in resource-constrained settings by delivering a CFIR 2.0- and NPT-guided, mechanism-focused analysis of the multi-level determinants that shape adoption, integration into routine PHC workflows, and long-term institutionalization; generating generalizable insights across districts; and contributing methodological assets in the form of psychometrically validated implementation measurement scales (tool-specific and composite) with transparent scoring rules and invariance checks. Together, these outputs will provide an evidence-based roadmap for policymakers and practitioners—identifying leverage points such as leadership engagement, readiness, and support systems—to prioritize investments in training, supervision, infrastructure, and data use, thereby bridging the gap between the technological potential of the MDE and measurable, system-level impact.

Generalizability and External Validity

While this study is conducted in Burkina Faso, its findings are expected to have transferability to similar contexts. The study's generalizability stems from three features: First, theoretical grounding in CFIR 2.0 and NPT—frameworks validated across diverse settings—ensures findings are interpreted through broadly applicable constructs rather than context-specific idiosyncrasies. Second, the validated measurement instruments produced by this study are intentionally designed for adaptability; items reference generalizable implementation constructs (e.g., "perceived ease of use," "organizational readiness") rather than Burkina Faso-specific details. Third, the multilevel analytical approach explicitly models contextual variation (between districts, facilities, individuals), allowing identification of which findings are setting-dependent versus universal.

That said, we acknowledge limitations to generalizability: The MDE's specific configuration (choice of 9 tools, CommCare/DHIS2 platforms) may differ from digital ecosystems elsewhere; Burkina Faso's health system structure (CSPS as the PHC backbone, the gratuité policy) may not mirror other countries; and infrastructure constraints in the study districts may be more or less severe than other SSA settings.

Recommendation for adaptation: Researchers and policymakers in other contexts should adapt the study's approach—integrated ecosystem evaluation using CFIR/NPT with validated scales—rather than directly applying the specific findings without contextual consideration. Our instruments and methods provide a replicable template, while acknowledging that determinants and thresholds of "implementation success" may vary by setting.

Potential Implications of Expected Results

The expected results carry implications from near-term operational improvements to long-term health system strengthening. Validating key implementation drivers would justify targeted actions—such as upgrading infrastructure, refining workflows, and institutionalizing ongoing professional development—to deliver a more robust and responsive MDE rollout. Over time, sustained use of the MDE is poised to enhance data quality, streamline clinical and administrative processes, and improve accountability and resource use. Collectively, these gains can translate into measurable improvements in access to and quality of essential PHC services, inform scalable strategies for digital health investment, and contribute to system resilience and equity in resource-constrained settings.

Strengths of the Protocol

This protocol has several strengths that enhance its scientific rigor: a sequential explanatory mixed-methods design that integrates the breadth of quantitative findings with the descriptive depth of qualitative inquiry; explicit grounding in established frameworks (CFIR 2.0 and NPT) to structure a coherent analysis of implementation dynamics; a multi-level data collection strategy that captures perspectives from providers, managers, community health workers, as well as users of health services (pregnant women and children under five) to enable triangulation; and a firm commitment to rigorous psychometric development and validation of all implementation measurement scales, which strengthens internal validity, reliability, and the interpretability of quantitative results.

Potential Limitations of the Protocol

This protocol has several potential limitations. First, reliance on self-reported data introduces risk of social desirability bias; we will mitigate this through intensive enumerator training, neutral interviewing, and strict anonymity procedures. Second, the cross-sectional survey design is suitable for characterizing implementation at a point in time but limits causal inference; the subsequent qualitative phase is intended to contextualize and explain observed associations. Third, generalizability may be constrained to settings with comparable health system structures and digital readiness. Finally, logistical challenges—such as reaching remote sites and accommodating busy clinical schedules—may affect recruitment and timing, necessitating flexible fieldwork plans and persistent follow-up.

Dissemination Strategies for Future Results

We will pursue a multi-audience strategy. For policymakers and program managers, comprehensive evaluation reports and concise policy briefs will be delivered to the Ministry of Health, district authorities, and funding partners. For frontline providers and communities, we will convene interactive feedback workshops to review the results and discuss the practical implications. To contribute to the global evidence base, we will publish in reputable peer-reviewed journals (including this protocol) and present at major international health conferences. To engage the public and media, we will produce plain-language summaries and fact sheets for broad distribution. Where permissible, we will share an anonymized dataset under a Data Use Agreement to support secondary analyses and reproducibility.

CONCLUSIONS

This protocol outlines a pivotal study to evaluate the implementation of a national digital health ecosystem in Burkina Faso. By generating robust evidence on implementation maturity, fidelity, and their key determinants, the research will directly inform optimization of the Minimal Digital Ecosystem and guide future digital health strategies. Ultimately, these insights are expected to support stronger, more equitable primary health care across sub-Saharan Africa.

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AI disclosure

The authors utilized ChatGPT (OpenAI) to assist with translation (French to English) and to enhance grammar and readability. All content was reviewed and approved by the authors, who take full responsibility for the final manuscript.

Conflicts of Interest

MC (Gates Foundation) is the study's grant manager. He contributed to critical manuscript revisions, approved the final version, and accepted accountability for the work. The funder had no role in the study's design, implementation, data collection, analysis, or interpretation, nor in the decision to submit the manuscript or the choice of journal.

Data Availability Statement

In line with principles of responsible data sharing, the final, anonymized dataset supporting the conclusions of this study, along with relevant metadata and documentation, will be preserved for future scientific use. As data collection is ongoing, the data is not currently available. However, upon completion of the study, interested researchers may submit a formal request for data access to the corresponding author. Access will be managed through a Data Use Agreement to ensure compliance with ethical standards and to protect participant privacy, thereby encouraging collaboration while maintaining data security.

Authors' Contributions

Conceptualization and protocol development: DZ, RK, IK, ST, CT, OS

Methodology: DZ (Quant Lead), RK, IK, ST, CT (supporting), YK (Qual Lead)

Software: DZ, TP, RN

Validation: DZ, YK, RK, ST, IK, JAK (supporting)

Investigation: IK (lead Field Coordinator)

Data curation: TP, RN

Writing – original draft: DZ, IK, ST, RK, OS, CT

Writing – review & editing: All authors

Supervision: DZ (PI), RK(Co-PI), IK, YK

Project administration: [YK]

Funding acquisition: JAK, PY

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Abbreviations

- ASBC: Agent de Santé à Base Communautaire (Community-Based Health Worker)
- CFIR: Consolidated Framework for Implementation Research
- CNER: Comité National d'Éthique pour la Recherche en Santé (National Ethics Committee for Health Research)
- COPS: Centre de Santé et de Promotion Sociale (Primary Health and Social Promotion Center)
- ECD: Équipe Cadre de District (District Health Management Team)
- MDE: Minimal Digital Ecosystem
- FIS: Fiche Individuelle de Soins (Individual Care Sheet)
- ICP: Infirmier Chef de Poste (Head Nurse of Post)
- NPT: Normalization Process Theory
- REC-PCIME: Registre Électronique de Consultation - Prise en Charge Intégrée des Maladies de l'Enfant (Electronic Consultation Register - Integrated Management of Childhood Illness)
- TIDieR: Template for Intervention Description and Replication

Multimedia Appendix

This study is not an interventional clinical trial; however, the Minimal Digital Ecosystem (MDE) is a complex intervention whose implementation is being evaluated. Accordingly, we adapted the SPIRIT 2013 guidance to structure the protocol, particularly the sections describing the intervention, objectives, outcomes, target population, and analysis plan. We also completed the TIDieR checklist to enable precise intervention reporting. The finalized checklists are provided as Multimedia Appendices.

- **Multimedia Appendix 1:** SPIRIT 2013 (adapted) checklist for an implementation study
- **Multimedia Appendix 2:** TIDieR checklist for the MDE intervention.

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Supplementary Files

Multimedia Appendixes

• Multimedia Appendix 1: SPIRIT 2013 (adapted) checklist for an implementation study • Multimedia Appendix 2: TIDieR checklist for the MDE intervention.

URL: <http://asset.jmir.pub/assets/317674c9ccf95806211b8e5580b50832.docx>