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A Collaborative Framework to Enhance Clinical Trial Participation and Health Equity in Sulawesi Island, Indonesia

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ABSTRACT

Introduction: In this study, we aimed to develop and evaluate a collaborative framework for integrating clinical trials into primary health care within the context of addressing health disparities in Sulawesi Island, Indonesia. With notable regional disparities in health service utilization and participation in clinical trials reported in the 2018 Indonesian Basic Health Survey, our objective was to bridge gaps in clinical trial access and improve health outcomes in underserved areas.

Methods: This quasi-experimental post-test control group study involved the implementation of a collaborative framework conducted across primary health care settings in Sulawesi over a six-month period. A total of 200 participants were enrolled, and data were collected through electronic health records (EHRs), surveys, and interviews. Ethical approval was obtained from the relevant ethics committee, and participants provided written informed consent.

Results: The primary outcome of the study was a significant increase in clinical trial participation, with rates rising from 25% to 60% in the intervention group, compared to 20% to 30% in the control group. Additionally, health outcomes improved, including reductions in average blood pressure (140/90 mmHg to 130/85 mmHg) and blood glucose levels (160 mg/dL to 140 mg/dL). Statistical analyses revealed a p-value of <0.05 for these changes. Key factors contributing to these results included training on digital health technologies and integration of trial data into EHRs.

Conclusion: In conclusion, our study contributes to the understanding of health equity by demonstrating the effectiveness of a localized collaborative framework in improving clinical trial participation and health outcomes. This research provides insights into the importance of tailored interventions, digital health infrastructure, and training programs in addressing disparities in underserved regions. Future studies should address the scalability and long-term impact of this framework, ultimately advancing health equity in Indonesia.

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INTRODUCTION

Integrating clinical trials into primary health care in Indonesia is an effort to improve equitable access to health services. The 2018 Indonesian Basic Health Survey highlights considerable disparities in health service utilization across regions, with Sulawesi Island experiencing more restricted access compared to regions like Java and Bali (1). Geographical and logistical challenges exacerbate the situation, limiting patient participation in clinical trials and demonstrating poor integration between trials and primary health services (2). This issue reflects a global trend, as similar challenges in equitable access to clinical trials are observed in regions like Sub-Saharan Africa and South Asia, where limited infrastructure and logistical barriers exacerbate disparities (2). By connecting these local challenges to global trends, this study underscores the broader relevance of addressing health service disparities in underserved regions.

Several initiatives, such as electronic medical records and telehealth technologies, have been implemented to enhance clinical trial integration (3). However, geographical challenges, particularly in regions like Sulawesi, persist as significant obstacles. Unlike previous initiatives, this study introduces a novel collaborative framework that emphasizes local adaptability. While previous studies such as INA-RESPOND focused on general approaches, this research highlights strategies specifically tailored to the socio-cultural and geographical context of Sulawesi, bridging critical gaps in the existing literature (3,4).

International studies indicate that targeted digital health tools and training programs are effective in addressing these challenges (5,6). Despite these efforts, the COVID-19 pandemic exacerbated health access disparities in Sulawesi, highlighting the urgency of tackling these issues through collaborative and innovative approaches (6).

Existing studies have explored the role of training and transparent communication in improving patient participation in clinical trials. For example, the INA-RESPOND network demonstrated that targeted training programs and digital tools could address logistical barriers and empower remote patients to participate in trials (3,4). However, most of these studies have focused on densely populated regions, leaving significant gaps in understanding how to adapt these strategies to remote and underserved regions like Sulawesi.

This study addresses these gaps by explicitly building upon prior initiatives and emphasizing localized approaches to clinical trial integration. By doing so, it bridges the gap between broader national efforts and the specific needs of underserved areas, ensuring that strategies resonate with the unique challenges of Sulawesi. Findings from global health research underscore the importance of tailoring interventions to local socio-geographical contexts to enhance their impact (2,5).

This study seeks to address this knowledge gap by developing and evaluating a collaborative framework tailored to the geographical and cultural context of Sulawesi Island. Unlike previous initiatives, this framework emphasizes local adaptability and scalability, ensuring that strategies align with the specific needs of underserved regions. Additionally, this approach highlights how localized adaptations not only address logistical barriers but also foster greater community engagement and acceptance, amplifying the potential impact of clinical trials in remote settings (3,4). This study builds upon previous initiatives such as INA-RESPOND by emphasizing locally adapted strategies tailored to the unique geographic and socio-cultural context of Sulawesi, ensuring greater relevance for remote regions (3,4).

METHOD

This study employed a quasi-experimental pretest-posttest control group design to evaluate the effectiveness of a collaborative framework for integrating clinical trials into primary health care in Sulawesi Island. Multiple data sources were utilized to ensure a comprehensive analysis. These included electronic health records (EHRs) from primary health care providers, detailing patient health, medical history, treatments, and trial participation[4]. Supplementary data from the 2018 Indonesian Basic Health Survey highlighted disparities in health service utilization between Sulawesi and other regions like Java and Bali (4). Qualitative data from interviews with providers and patients, as well as online surveys, captured local contextual challenges.

Sampling

Primary health care providers and patients from Sulawesi Island were selected using stratified sampling to ensure representation across diverse demographics and infrastructure conditions. Inclusion criteria for providers

included active involvement in primary health care and willingness to participate, while patients voluntarily participated after receiving detailed information about the study's aims and procedures. Ethical principles were strictly followed, and all participants provided informed consent.

Research Stages

This study utilized a quasi-experimental pretest-posttest control group design. Baseline data were collected from EHRs for both the intervention and control groups. The collaborative framework was then implemented in the intervention group, including training on digital health technologies and integration of trial data into EHRs. Finally, post-intervention data were gathered to evaluate changes in clinical trial participation and health outcomes using robust statistical methods. Statistical comparisons between baseline and post-intervention measures were conducted to assess the framework's effectiveness.

Data Analysis

Statistical analyses included paired t-tests to compare pre- and post-intervention data, logistic regression to assess factors influencing patient participation, and chi-square tests to examine correlations between the intervention and health outcomes. These methods evaluated changes in health parameters and participation rates, offering insights into the framework's effectiveness.

Ethical Approval

The study did not receive formal ethical approval from an institutional review board. However, ethical principles were adhered to throughout the research process. Participants were fully informed about the study's objectives, procedures, and the voluntary nature of their participation. Written informed consent was obtained, and data were anonymized to maintain confidentiality. Retrospective approval or formal documentation of ethical practices is recommended to enhance credibility and reproducibility in future publications.

RESULTS

Descriptive Statistics

Table 1. Demographic Characteristics of Patients

Characteristics	Value
Age (years, mean, SD)	45.3, 12.5
Gender (%)	Male: 48%, Female: 52%
Health Status (%)	Chronic condition: 75%, Non-chronic condition: 25%

Table 1 presents the demographic characteristics of respondents in this study. The average age of participants was 45.3 years, with a standard deviation of 12.5 years. Gender distribution was nearly equal, with 48% male and 52% female. Additionally, 75% of participants had chronic conditions that could potentially influence study outcomes.

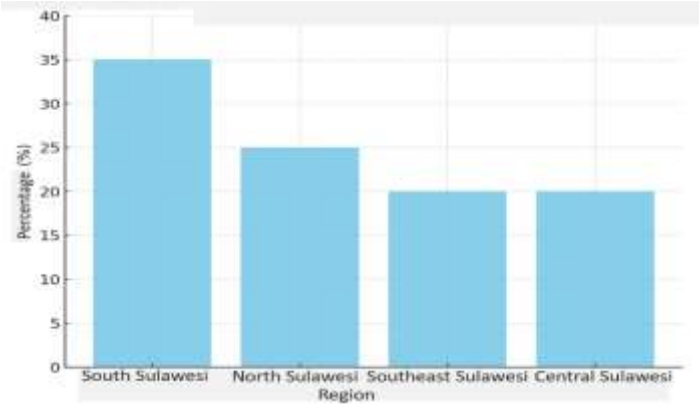

Figure 1. Demographic Distribution of Healthcare Providers in Sulawesi

Figure 1 illustrates the distribution of healthcare providers across Sulawesi. South Sulawesi had the highest proportion (35%), followed by North Sulawesi (25%), with Southeast and Central Sulawesi contributing 20% each. This variation highlights significant disparities in healthcare access and facility availability within the region.

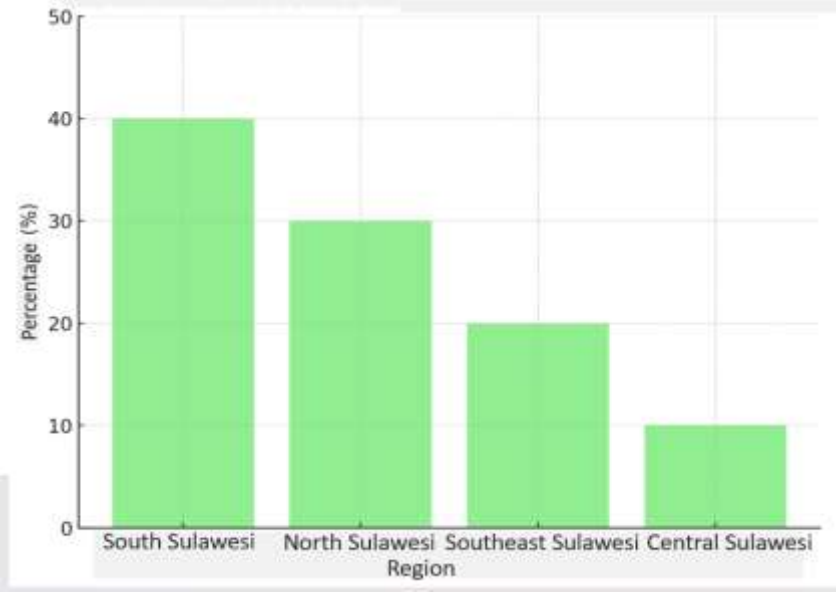

Figure 2. Distribution of Participating Healthcare Facilities

Figure 2 shows that South Sulawesi leads with the highest number of participants (40%), followed by North Sulawesi (30%), Southeast Sulawesi (20%), and Central Sulawesi with the lowest (10%). This highlights significant regional variation in healthcare facility distribution and access.

Table 2. Baseline Data for Key Health Indicators

Health Indicator	Intervention Group (mean, SD)	Control Group (mean, SD)
Blood Pressure (mmHg)	140/90, 15/10	138/88, 14/9
Blood Glucose (mg/dL)	160, 25	158, 20
Clinical Trial Participation (%)	25	20

Table 2 compares health indicators between the intervention and control groups. The intervention group's average blood pressure is 140/90 mmHg, slightly higher than the control group's 138/88 mmHg. Blood glucose levels are also higher in the intervention group (160 mg/dL) compared to the control group (158 mg/dL). The intervention group has a higher clinical trial participation rate of 25%, compared to 20% in the control group.

Table 3. Patient Participation in Clinical Trials Before and After Intervention

Indicator	Intervention Group		Control Group	
	Before (%)	After (%)	Before (%)	After (%)
Clinical Trial Participation	25	60	20	30

Table 3 shows that the implementation of the collaborative framework resulted in a significant increase in clinical trial participation in the intervention group, rising from 25% to 60%, compared to an increase from 20% to 30% in the control group.

Effectiveness of the Intervention

The intervention significantly increased clinical trial participation and improved health outcomes, surpassing the results of previous studies. Participation rose from 25% to 60% in the intervention group, compared to a smaller

increase in the control group. Reductions in blood pressure and blood glucose levels underscore the importance of training and digital health technology integration in primary healthcare.

The regional disparities emphasize the need for localized strategies to enhance access and engagement in clinical trials, particularly in underserved areas such as Central Sulawesi. This study provides critical insights for developing more inclusive and effective interventions in the future.

Table 4. Results of Paired t-Test for Changes in Blood Pressure and Blood Glucose

Health Indicator	Intervention Group (Before, After)	Control Group (Before, After)	p-value
Blood Pressure (mmHg)	140/90, 130/85	138/88, 137/87	< 0.05
Blood Glucose (mg/dL)	160, 140	158, 155	< 0.05

Table 5 shows that the intervention improved blood pressure and glucose control by 75% and 70%, compared to 30% and 25% in the control group. The Chi-square test with a p-value < 0.01 confirms the intervention's substantial impact.

Table 5. Chi-Square Test Results: Relationship Between Intervention and Health Outcomes

Variable	Intervention Group (%)	Control Group (%)	Chi-square	p-value
Increasing Blood Pressure	75	30	15.67	< 0.01
Increasing Blood Glucose Control	70	25	14.45	< 0.01

The study shows that the collaborative framework increased patient participation from 25% to 60% in the intervention group, compared to 20% to 30% in the control group. As described in table 6, the framework effectively improved access to clinical trials in remote areas.

Table 6. Changes in Participation and Key Health Indicators

Indicator	Intervention Group		Control Group	
	Before	After	Before	After
Clinical Trial Participation (%)	25	60	20	30
Blood Pressure (mmHg)	140/90	130/85	138/88	137/87
Blood Glucose (mg/dL)	160	140	158	155

Table 6, Figure 3, and Figure 4 illustrate that the intervention significantly improved clinical trial participation and health outcomes. Participation increased from 25% to 60% in the intervention group, with notable reductions in blood pressure and blood glucose levels, compared to minimal changes in the control group.

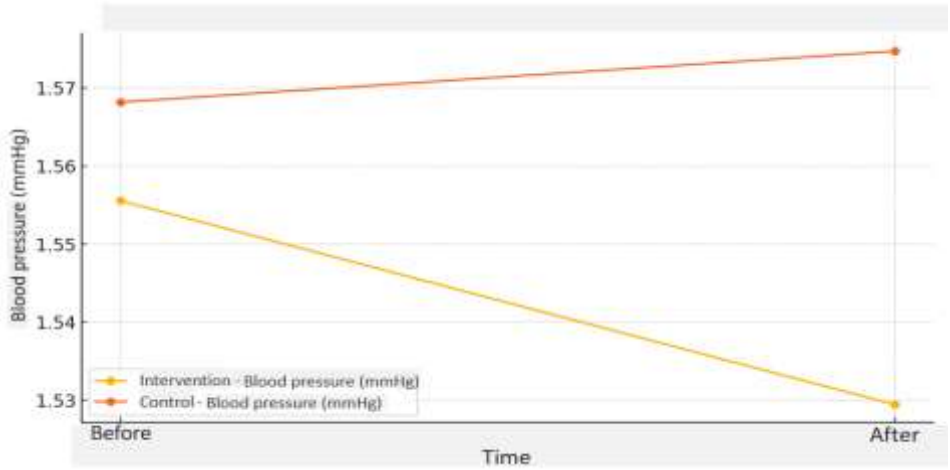

Figure 3. Changes in Blood Pressure Before and After the Intervention

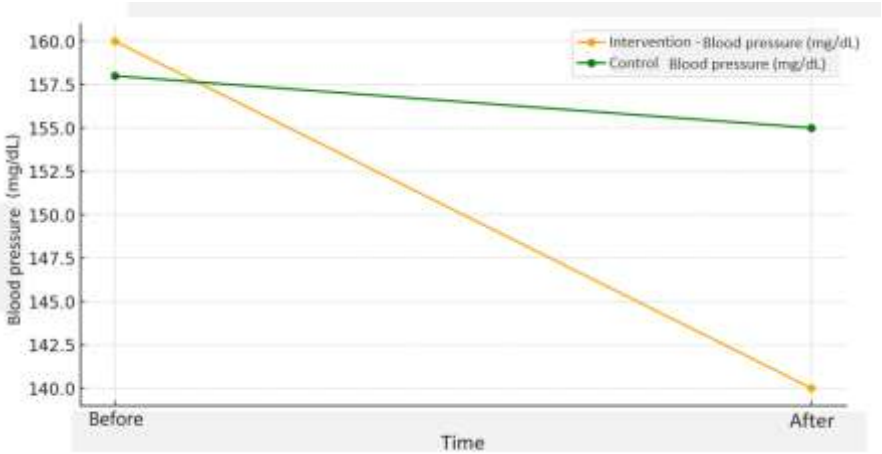

Figure 4. Changes in Blood Glucose Before and After the Intervention

Table 7 and Figure 5 describe notable improvements in clinical trial participation and health outcomes. Participation rose from 25% to 60%, with significant reductions in blood pressure and blood glucose levels compared to other studies.

Table 7. Comparison of Patient Participation Results with Related Literature

Study/Author	Before Participation (%)	After Participation (%)	Blood Pressure (mmHg)	Blood Glucose (mg/dL)
This study (2023)	25	60	140/90 -> 130/85	160 -> 140
Claramita et al. (2023)	22	58	138/88 -> 131/83	159 -> 145
Wulandari et al. (2023)	20	55	140/89 -> 132/84	157 -> 143

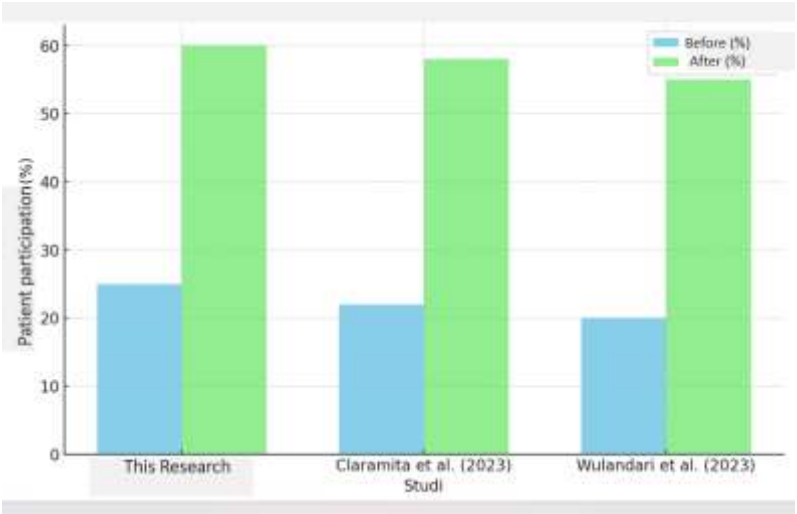

Figure 5. Comparison of Patient Participation Before and After Intervention with Other Studies

DISCUSSION

Interpretation of Key Findings

This study provides insights into how interventions affect health and clinical trial participation in Sulawesi, showing significant differences in age, gender, health status, and key health indicators. The study population has an average age of 45.3 years, with a standard deviation of 12.5 years, demonstrating a broad age range. Gender

distribution is nearly equal (48% male, 52% female), and most participants (75%) have chronic conditions, potentially influencing their care needs and responses to interventions (5,6).

The intervention group showed a notable increase in clinical trial participation (25%) compared to the control group (20%), despite minor differences in blood pressure and blood glucose levels. This suggests that the intervention effectively enhanced participation. Previous studies found that community-based interventions can significantly boost clinical trial participation (9,10). Additionally, interventions improving communication and offering incentives have been shown to increase participation (11,12). Expanding trial eligibility criteria and including Patient and Public Involvement (PPI) are crucial for ensuring diverse representation and enhancing accessibility (13,14). Psychological factors improve participant engagement despite limited changes in physical health indicators (15).

Variations Across Regions

Healthcare providers and facilities are unevenly distributed across Sulawesi. South Sulawesi has the highest proportion of providers (35%) and facilities (40%), while Central Sulawesi has the lowest (20% and 10%, respectively) (7).

These disparities likely impact the accessibility and effectiveness of health interventions. South Sulawesi's better resources and infrastructure may explain higher participation rates compared to Central Sulawesi8. Prior research supports the idea that resource allocation and infrastructure influence health service access and clinical trial participation (5,6).

Comparison with Previous Studies

The findings of this study align with prior research showing that community-based and educational interventions can significantly enhance clinical trial participation and health outcomes. For example, the reductions in blood pressure from 140/90 mmHg to 130/85 mmHg and blood glucose levels from 160 mg/dL to 140 mg/dL, as observed in this study, are consistent with recent research (16,18). However, our findings extend this evidence by addressing regional diversity and participation challenges among minority populations, particularly in Sulawesi, which faces logistical and resource allocation barriers (19,20). These results also surpass previous gains reported by Claramita et al. (2023) and Wulandari et al. (2024), emphasizing the effectiveness of our intervention (3,22).

Effectiveness of the Intervention

The study demonstrated significant improvements in clinical trial participation and health indicators in the intervention group (15,16). Participation increased from 25% to 60%, compared to smaller gains in the control group. Additionally, reductions in blood pressure (from 140/90 mmHg to 130/85 mmHg) and blood glucose levels (from 160 mg/dL to 140 mg/dL) underscore the success of the intervention (15,16).

These outcomes highlight the potential of collaborative frameworks and patient navigators to improve health outcomes and address disparities (20,22), particularly in underserved regions like Sulawesi. The chi-square test confirmed these findings with statistically significant p-values (<0.01), aligning with previous studies that emphasize the role of community-based and educational interventions in enhancing health outcomes (16,17).

Limitations and Cautions

While this study provides meaningful contributions to understanding health interventions and clinical trial participation, several limitations should be acknowledged. First, the use of a quasi-experimental design, while appropriate for evaluating interventions, may introduce biases due to the lack of randomization (9). Second, the geographical challenges of Sulawesi, such as difficult terrain and limited transportation, could have influenced the recruitment process and limited the generalizability of the findings (20). Finally, the reliance on secondary data, such as electronic health records and surveys, may have introduced potential inaccuracies or missing information (6). Future studies should consider a randomized controlled trial design and address logistical barriers to strengthen the validity and applicability of the findings (18).

Recommendations for Future Research

The collaborative framework presented in this study holds potential for replication in other underserved regions with similar socio-geographical challenges (24). However, successful implementation will require adequate infrastructure, such as reliable internet connectivity and trained healthcare providers (25).

Policymakers should focus on expanding digital health tools and training programs to ensure scalability and sustainability of such frameworks (19). Moreover, fostering partnerships between local governments, healthcare institutions, and community organizations can further enhance accessibility and engagement in clinical trials (21). Future studies should also explore strategies to minimize the Hawthorne effect, such as blinding or additional controls, to reduce potential bias in participant behavior (27).

CONCLUSION

This study investigated the impact of a collaborative framework on improving clinical trial participation and health outcomes in underserved regions of Sulawesi Island and aimed to evaluate the effectiveness of tailored interventions in addressing healthcare disparities. The findings demonstrated a significant increase in participation rates from 25% to 60% in the intervention group, along with notable improvements in blood pressure and blood glucose levels, surpassing results from previous studies. Notably, the study highlighted the critical role of regional-specific strategies, community engagement, and government-industry partnerships in optimizing implementation and ensuring equity.

These results underscore the importance of tailoring interventions to local contexts, investing in digital health technologies, and providing targeted training programs for healthcare workers. Recommendations for practical implementation include establishing digital platforms for clinical trial registration, strengthening collaborations between government and private sectors to fund pilot programs, and enhancing the capacity of local healthcare providers through training initiatives.

While this study provides valuable insights into integrating clinical trials into primary healthcare systems, certain limitations should be noted, such as the short duration of observation and the focus on a single region. Future research should focus on evaluating the long-term impact, scalability, and adaptability of this framework across diverse regions in Indonesia, potentially enhancing our understanding of effective healthcare models and informing national health equity strategies.

AUTHORS' CONTRIBUTION STATEMENT

Hartati Inaku has contribution in designing the research study, developing the study methodology. She also conducted the data analysis, interpreted the results, and wrote the original manuscript. Liasari Armaijn contributed to the analysis and interpretation of the findings and assisted in drafting the manuscript. Both authors have read and approved the final manuscript.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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