Preventing Postpartum Depression: Exercise is Medicine

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1. Protocol

Protocol Title

Preventing Postpartum Depression: Exercise as Medicine

Principal Investigator

Lyndsay Avalos, PhD, MPH

Version Date

10/21/2020

Form Author

Crystal Hsiao

2. Objectives

Describe in plain language the purpose, specific aims, or objectives and indicate the primary goal(s) of the study (e.g. safety, tolerability, effectiveness, feasibility, pilot study, etc.). State the hypotheses to be tested. State primary and any secondary study endpoints.

The purpose of this study is to address a high priority area of the KP-NBA Exercise as Medicine initiative and the critical need for evidence-based interventions for increasing physical activity (PA) and preventing postpartum depression (PPD) that do not involve intense health care system resources through the aims below. This study will also identify actionable avenues for implementation of this eHealth PA intervention at KPNC and potentially other KP regions in the future.

Aim 1. Conduct an effectiveness trial of MomZing, an eHealth PA intervention, in women at increased risk of postpartum depression (PPD) for a) increasing PA and b) decreasing depressive symptoms.

Aim 2. Evaluate procedures for implementation of MomZing at KPNC. We will use the RE-AIM framework (**R**each, **E**ffectiveness, **A**doption, **I**mplementation, **M**aintenance) to evaluate procedures for implementation of MomZing including documentation of web access to MomZing exercise videos (website analytics), process measures (participant satisfaction with the

intervention), and qualitative interviews with KPNC clinical staff (barriers to adoption/maintenance).

Exploratory Aim 1: Assess the impact of MomZing on improving maternal outcomes (e.g. postpartum depression diagnoses, anxiety, stress, sleep, medical conditions, substance use, health care utilization) and infant outcomes (e.g. growth and development, health care utilization). Describe maternal and infant characteristics associated with greater levels of engagement/use of the MomZing intervention.

Exploratory Aim 2: Identify mediators and moderators (e.g. previous physical activity, maternal infant bonding, perceived barriers to physical activity, social support) in the relationship between MomZing and maternal and infant outcomes (as listed above).

Exploratory Aim 3: Assess relationships between exercise and other health behaviors (e.g. sleep, sitting, substance use, smoking) and maternal and infant outcomes.

3. Background

a. Scientific Background

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. A list of references or bibliography must be included as part of this document or uploaded separately.

Nearly 20% of postpartum women suffer from postpartum depression (PPD), a life-threatening, debilitating and costly mood disorder that emerges within a year of delivery.[40-42] PPD has a substantial impact on the health of mother and child including negative maternal-infant interaction,[43] lower likelihood of breastfeeding,[44,45] and completing recommended immunizations.[45] PPD is also associated with child behavioral problems[7,45] and poorer cognitive development.[46-48] The national health care costs associated with PPD in 2017 were estimated at $2.9 billion for mothers and $4.9 billion for their children.[13] Importantly, the US Preventive Services Task Force recognized that PPD is preventable and issued a recommendation to refer women at increased risk of PPD (those with a history of depression prior to pregnancy or at least moderate postpartum depressive symptoms that do not meet the diagnostic threshold for PPD) to counseling services.[16] Our team responded in a JAMA Pediatrics Editorial[17] highlighting the urgent need to identify other evidence-based preventive interventions, such as PA interventions, that may not involve intense health care system resources.

Strong evidence suggests postpartum PA is effective in preventing PPD;[18-21,49,50] however, several barriers to PA keep postpartum women from being physically active. The PA Guidelines for Americans,[24] the American College of Sports Medicine,[51] and the American College of Obstetricians and Gynecologists[23] recommend participation in regular PA (at least 150 minutes of moderate to vigorous intensity per week) for postpartum women. Despite these recommendations, PA levels in postpartum women remain low: only one third of postpartum women report being regularly physically active in the year after delivery.[28-30] Low postpartum rates of PA contribute to postpartum weight retention, overweight, and obesity.[52,53] We conducted focus groups among KPNC members with PPD and found similar barriers to PA during the postpartum period as has been reported by others: lack of time and prioritization of other responsibilities, difficulty finding accessible and affordable PA programs and classes, lack of child care, and lack of motivation and social support.[54-57] Most previous PA interventions in

postpartum women have relied on in-person exercise groups alone or in combination with individual in-person or telephone-based health coaching.[18,19] These approaches do not address the barriers to being physically active identified in postpartum women.

Technology-based (eHealth) interventions are a promising approach to increasing PA levels that address barriers raised by postpartum women. New mothers are frequent users of technology and welcome eHealth interventions.[58,59] eHealth PA interventions have demonstrated effectiveness in increasing PA in general populations.[31,32] In addition, MomZing, an eHealth intervention tailored to postpartum women, was effective in increasing the proportion of postpartum women meeting national PA guidelines.[33] MomZing was developed by exercise physiologists and behavioral medicine specialists and addresses accessibility, affordability, time constraints, and child care concerns.

REFERENCES

1. Horowitz JA, Goodman J. A longitudinal study of maternal postpartum depression symptoms. *Res Theory Nurs Pract.* 2004;18(2-3):149-163.
2. Kumar R, Robson KM. A prospective study of emotional disorders in childbearing women. *Br J Psychiatry.* 1984;144:35-47.
3. Davidson J, Robertson E. A follow-up study of post partum illness, 1946-1978. *Acta Psychiatr Scand.* 1985;71(5):451-457.
4. Cooper PJ, Murray L. Course and recurrence of postnatal depression. Evidence for the specificity of the diagnostic concept. *Br J Psychiatry.* 1995;166(2):191-195.
5. Uddenberg N, Englesson I. Prognosis of post partum mental disturbance. A prospective study of primiparous women and their 4 1/2-year-old children. *Acta Psychiatr Scand.* 1978;58(3):201-212.
6. Stein A, Gath DH, Bucher J, Bond A, Day A, Cooper PJ. The relationship between post-natal depression and mother-child interaction. *Br J Psychiatry.* 1991;158:46-52.
7. Murray L. The impact of postnatal depression on infant development. *Journal of child psychology and psychiatry, and allied disciplines.* 1992;33(3):543-561.
8. Stein A, Malmberg LE, Sylva K, Barnes J, Leach P, team** F. The influence of maternal depression, caregiving, and socioeconomic status in the post-natal year on children's language development. *Child Care Health Dev.* 2008;34(5):603-612.
9. Hay DF, Pawlby S, Sharp D, Asten P, Mills A, Kumar R. Intellectual problems shown by 11-year-old children whose mothers had postnatal depression. *J Child Psychol Psychiatry.* 2001;42(7):871-889.
10. Grace SL, Evindar A, Stewart DE. The effect of postpartum depression on child cognitive development and behavior: a review and critical analysis of the literature. *Arch Womens Ment Health.* 2003;6(4):263-274.
11. Farias-Antunez S, Xavier MO, Santos IS. Effect of maternal postpartum depression on offspring's growth. *J Affect Disord.* 2018;228:143-152.
12. Balbierz A, Bodnar-Deren S, Wang JJ, Howell EA. Maternal depressive symptoms and parenting practices 3-months postpartum. *Matern Child Health J.* 2015;19(6):1212-1219.
13. Luca DL, Garlow N, Staatz C, Margiotta C, Zivin K. Societal Costs of Untreated Perinatal Mood and Anxiety Disorders in the United States. *Mathematica Policy Research.* 2019.
14. Leigh B, Milgrom J. Risk factors for antenatal depression, postnatal depression and parenting stress. *BMC Psychiatry.* 2008;8:24.

15. Nakic Rados S, Herman R, Tadinac M. Is the Predictability of New-Onset Postpartum Depression Better During Pregnancy or in the Early Postpartum Period? A Prospective Study in Croatian Women. *Health Care Women Int.* 2016;37(1):23-44.
16. Curry SJ, Krist AH, Owens DK, et al. Interventions to Prevent Perinatal Depression: US Preventive Services Task Force Recommendation Statement. *Jama.* 2019;321(6):580-587.
17. Avalos LA, Flanagan T, Li DK. Preventing Perinatal Depression to Improve Maternal and Child Health-a Health Care Imperative. *JAMA Pediatr.* 2019.
18. Teychenne M, York R. Physical activity, sedentary behavior, and postnatal depressive symptoms: a review. *American journal of preventive medicine.* 2013;45(2):217-227.
19. McCurdy AP, Boule NG, Sivak A, Davenport MH. Effects of Exercise on Mild-to-Moderate Depressive Symptoms in the Postpartum Period: A Meta-analysis. *Obstetrics and gynecology.* 2017;129(6):1087-1097.
20. Poyatos-Leon R, Garcia-Hermoso A, Sanabria-Martinez G, Alvarez-Bueno C, Cavero-Redondo I, Martinez-Vizcaino V. Effects of exercise-based interventions on postpartum depression: A meta-analysis of randomized controlled trials. *Birth (Berkeley, Calif).* 2017;44(3):200-208.
21. Physical Activity Guidelines Advisory Committee. *Section F, Chapter 8. Women Who are Pregnant or Postpartum.* Washington, D.C: U.S. Department of Health and Human Services;2018.
22. Mammen G, Faulkner G. Physical activity and the prevention of depression: a systematic review of prospective studies. *American journal of preventive medicine.* 2013;45(5):649-657.
23. Committee on Obstetric Practice. ACOG committee opinion. Exercise during pregnancy and the postpartum period. Number 267, January 2002. American College of Obstetricians and Gynecologists. *Int J Gynaecol Obstet.* 2002;77(1):79-81.
24. U.S. *Physical Activity Guidelines for Americans, 2nd edition.* Washington, DC: U.S. Department of Health and Human Services; 2018.
25. Borodulin K, Evenson KR, Herring AH. Physical activity patterns during pregnancy through postpartum. *BMC women's health.* 2009;9:32.
26. Evenson KR, Herring AH, Wen F. Self-Reported and objectively measured physical activity among a cohort of postpartum women: the PIN Postpartum Study. *Journal of physical activity & health.* 2012;9(1):5-20.
27. Olson CM, Strawderman MS, Hinton PS, Pearson TA. Gestational weight gain and postpartum behaviors associated with weight change from early pregnancy to 1 y postpartum. *International journal of obesity and related metabolic disorders : journal of the International Association for the Study of Obesity.* 2003;27(1):117-127.
28. Hull EE, Rofey DL, Robertson RJ, Nagle EF, Otto AD, Aaron DJ. Influence of marriage and parenthood on physical activity: a 2-year prospective analysis. *Journal of physical activity & health.* 2010;7(5):577-583.
29. Albright C, Maddock JE, Nigg CR. Physical activity before pregnancy and following childbirth in a multiethnic sample of healthy women in Hawaii. *Women & health.* 2005;42(3):95-110.
30. Pereira MA, Rifas-Shiman SL, Kleinman KP, Rich-Edwards JW, Peterson KE, Gillman MW. Predictors of change in physical activity during and after pregnancy: Project Viva. *American journal of preventive medicine.* 2007;32(4):312-319.
31. Cotie LM, Prince SA, Elliott CG, et al. The effectiveness of eHealth interventions on physical activity and measures of obesity among working-age women: a systematic review and meta-analysis. *Obesity reviews : an official journal of the International Association for the Study of Obesity.* 2018;19(10):1340-1358.
32. Hakala S, Rintala A, Immonen J, Karvanen J, Heinonen A, Sjogren T. Effectiveness of physical activity promoting technology-based distance interventions compared to usual care. Systematic

review, meta-analysis and meta-regression. *European journal of physical and rehabilitation medicine.* 2017;53(6):953-967.
33. Albright C, Wilkens L, Saiki K, Tome A, Martin R, Dunn A. Increasing physical activity in new mothers via customizable online exercise videos: MomZing Results. *Annals of Behavioral Medicine.* 2015;49(Suppl):S89.
34. Albright C, Wilkens L, Saiki K, White K, Steffen A. Mediators of a 12-month change in physical activity in ethnically diverse sample of postpartum women. *Translational Journal of the American College of Sports Medicine.*In press.
35. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality and Safety in Health Care.* 2005;14(1):26-33.
36. Michie S, Atkins L, West R. *The behaviour change wheel: A guide to designing interventions.* London: Silverback Publishing; 2014.
37. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science.* 2012;7:37.
38. Flanagan T, Avalos LA. Perinatal Obstetric Office Depression Screening and Treatment: Implementation in a Health Care System. *Obstetrics and gynecology.* 2016;127(5):911-915.
39. Avalos LA, Raine-Bennett T, Chen H, Adams AS, Flanagan T. Improved Perinatal Depression Screening, Treatment, and Outcomes With a Universal Obstetric Program. *Obstetrics and gynecology.* 2016;127(5):917-925.
40. ACOG Committee Opinion No. 630: Screening for perinatal depression. *Obstetrics and Gynecology.* 2015;125(5):1268-1271.
41. Gavin NI, Gaynes BN, Lohr KN, Meltzer-Brody S, Gartlehner G, Swinson T. Perinatal depression: a systematic review of prevalence and incidence. *Obstetrics and gynecology.* 2005;106(5 Pt 1):1071-1083.
42. Gaynes BN, Gavin N, Meltzer-Brody S, et al. Perinatal depression: prevalence, screening accuracy, and screening outcomes. *Evid Rep Technol Assess (Summ).* 2005(119):1-8.
43. Beck CT. The effects of postpartum depression on maternal-infant interaction: a meta-analysis. *Nursing research.* 1995;44(5):298-304.
44. Grigoriadis S, VonderPorten EH, Mamisashvili L, et al. The impact of maternal depression during pregnancy on perinatal outcomes: a systematic review and meta-analysis. *The Journal of clinical psychiatry.* 2013;74(4):e321-341.
45. O'Hara MW, McCabe JE. Postpartum depression: current status and future directions. *Annual review of clinical psychology.* 2013;9:379-407.
46. Yonkers KA, Wisner KL, Stewart DE, et al. The management of depression during pregnancy: a report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists. *Obstetrics and gynecology.* 2009;114(3):703-713.
47. Quevedo LA, Silva RA, Godoy R, et al. The impact of maternal post-partum depression on the language development of children at 12 months. *Child: care, health and development.* 2012;38(3):420-424.
48. Murray L, Cooper PJ. Postpartum depression and child development. *Psychological medicine.* 1997;27(2):253-260.
49. Pritchett RV, Daley AJ, Jolly K. Does aerobic exercise reduce postpartum depressive symptoms? a systematic review and meta-analysis. *The British journal of general practice : the journal of the Royal College of General Practitioners.* 2017;67(663):e684-e691.
50. Davenport MH, McCurdy AP, Mottola MF, et al. Impact of prenatal exercise on both prenatal and postnatal anxiety and depressive symptoms: a systematic review and meta-analysis. *Br J Sports Med.* 2018;52(21):1376-1385.

51. American College of Sports Medicine. *ACSM's Guidelines for Exercise Testing and Prescription.* 10 ed. Philadelphia: Wolters Kluwer; 2018.
52. Minig L, Trimble EL, Sarsotti C, Sebastiani MM, Spong CY. Building the evidence base for postoperative and postpartum advice. *Obstetrics and gynecology.* 2009;114(4):892-900.
53. O'Toole ML, Sawicki MA, Artal R. Structured diet and physical activity prevent postpartum weight retention. *Journal of women's health (2002).* 2003;12(10):991-998.
54. Leiferman J, Swibas T, Koiness K, Marshall JA, Dunn AL. My baby, my move: examination of perceived barriers and motivating factors related to antenatal physical activity. *Journal of midwifery & women's health.* 2011;56(1):33-40.
55. Albright CL, Saiki K, Steffen AD, Woekel E. What barriers thwart postpartum women's physical activity goals during a 12-month intervention? A process evaluation of the Na Mikimiki Project. *Women & health.* 2015;55(1):1-21.
56. Evenson KR, Aytur SA, Borodulin K. Physical activity beliefs, barriers, and enablers among postpartum women. *Journal of women's health (2002).* 2009;18(12):1925-1934.
57. Saligheh M, McNamara B, Rooney R. Perceived barriers and enablers of physical activity in postpartum women: a qualitative approach. *BMC pregnancy and childbirth.* 2016;16(1):131.
58. Fernandez N, Copenhaver DJ, Vawdrey DK, Kotchoubey H, Stockwell MS. Smartphone Use Among Postpartum Women and Implications for Personal Health Record Utilization. *Clinical pediatrics.* 2017;56(4):376-381.
59. Hogue J, Benezra K. *The Digital Lives of Power Moms.* 2009.
60. Gilinsky AS, Dale H, Robinson C, Hughes AR, McInnes R, Lavallee D. Efficacy of physical activity interventions in post-natal populations: systematic review, meta-analysis and content coding of behaviour change techniques. *Health psychology review.* 2015;9(2):244-263.
61. Davis R, Campbell R, Hildon Z, Hobbs L, Michie S. Theories of behaviour and behaviour change across the social and behavioural sciences: a scoping review. *Health psychology review.* 2015;9(3):323-344.
62. Greaney ML, Puleo E, Sprunck-Harrild K, Haines J, Houghton SC, Emmons KM. Social Support for Changing Multiple Behaviors: Factors Associated With Seeking Support and the Impact of Offered Support. *Health education & behavior : the official publication of the Society for Public Health Education.* 2018;45(2):198-206.
63. Courneya KS, Plotnikoff R, Hotz S, Birkett N. Social support and the theory of planned behavior in the exercise domain. *American Journal of Health Behavior.* 2000;24(4):300-308.
64. Shaw LH, Gant LM. In defense of the internet: the relationship between Internet communication and depression, loneliness, self-esteem, and perceived social support. *Cyberpsychology & behavior : the impact of the Internet, multimedia and virtual reality on behavior and society.* 2002;5(2):157-171.
65. Cole DA, Nick EA, Zelkowitz RL, Roeder KM, Spinelli T. Online Social Support for Young People: Does It Recapitulate In-person Social Support; Can It Help? *Computers in human behavior.* 2017;68:456-464.
66. Rovniak LS, Sallis JF, Kraschnewski JL, et al. Engineering online and in-person social networks to sustain physical activity: application of a conceptual model. *BMC public health.* 2013;13:753.
67. Valero-Elizondo J, Salami JA, Osondu CU, et al. Economic Impact of Moderate-Vigorous Physical Activity Among Those With and Without Established Cardiovascular Disease: 2012 Medical Expenditure Panel Survey. *Journal of the American Heart Association.* 2016;5(9).
68. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American journal of public health.* 1999;89(9):1322-1327.

69. Albright CL, Dunn AL, Edwards E, Kadowaki J, Martin R. Designing multimedia internet-based technology to increase physical activity in new mothers: The MomZing Program. *Obesity Rev.* 2010;11(Suppl 1):450.
70. Cummins J, Dunn AL, Martin R, Albright CL, Saiki K, Shane J. Designing an effective physical activity intervention using the Google TV-putting user input at the forefront. . *J Sci Med Sport.* 2012;15(6):338.
71. Samdal GB, Eide GE, Barth T, Williams G, Meland E. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. *Int J Behav Nutr Phys Act.* 2017;14(1):42.
72. Brown SD, Hedderson MM, Ehrlich SF, et al. Gestational weight gain and optimal wellness (GLOW): rationale and methods for a randomized controlled trial of a lifestyle intervention among pregnant women with overweight or obesity. *BMC pregnancy and childbirth.* 2019;19(1):145.
73. Conway MR, Marshall MR, Schlaff RA, Pfeiffer KA, Pivarnik JM. Physical Activity Device Reliability and Validity during Pregnancy and Postpartum. *Medicine and science in sports and exercise.* 2018;50(3):617-623.
74. Vandesompele J, De Preter K, Pattyn F, et al. Accurate normalization of real-time quantitative RT-PCR data by geometric averaging of multiple internal control genes. *Genome biology.* 2002;3(7):Research0034.
75. Choi L, Ward SC, Schnelle JF, Buchowski MS. Assessment of wear/nonwear time classification algorithms for triaxial accelerometer. *Medicine and science in sports and exercise.* 2012;44(10):2009-2016.
76. Choi L, Liu Z, Matthews CE, Buchowski MS. Validation of accelerometer wear and nonwear time classification algorithm. *Medicine and science in sports and exercise.* 2011;43(2):357-364.
77. Troiano RP, Berrigan D, Dodd KW, Masse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. *Medicine and science in sports and exercise.* 2008;40(1):181-188.
78. Sasaki JE, John D, Freedson PS. Validation and comparison of ActiGraph activity monitors. *Journal of science and medicine in sport / Sports Medicine Australia.* 2011;14(5):411-416.
79. Craig CL, Marshall AL, Sjostrom M, et al. International physical activity questionnaire: 12-country reliability and validity. *Medicine and science in sports and exercise.* 2003;35(8):1381-1395.
80. *Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire (IPAQ).* 2005.
81. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine.* 2001;16(9):606-613.
82. Spitzer RL, Williams JB, Kroenke K, Hornyak R, McMurray J. Validity and utility of the PRIME-MD patient health questionnaire in assessment of 3000 obstetric-gynecologic patients: the PRIME-MD Patient Health Questionnaire Obstetrics-Gynecology Study. *American journal of obstetrics and gynecology.* 2000;183(3):759-769.
83. Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire. *Jama.* 1999;282(18):1737-1744.
84. Gilbody S, Richards D, Brealey S, Hewitt C. Screening for depression in medical settings with the Patient Health Questionnaire (PHQ): a diagnostic meta-analysis. *J Gen Intern Med.* 2007;22(11):1596-1602.

85. Wittkampf KA, Naeije L, Schene AH, Huyser J, van Weert HC. Diagnostic accuracy of the mood module of the Patient Health Questionnaire: a systematic review. *General hospital psychiatry.* 2007;29(5):388-395.
86. Lowe B, Unutzer J, Callahan CM, Perkins AJ, Kroenke K. Monitoring depression treatment outcomes with the patient health questionnaire-9. *Med Care.* 2004;42(12):1194-1201.
87. Roozenbeek B, Maas AI, Lingsma HF, et al. Baseline characteristics and statistical power in randomized controlled trials: selection, prognostic targeting, or covariate adjustment? *Crit Care Med.* 2009;37(10):2683-2690.
88. Hernandez AV, Steyerberg EW, Habbema JD. Covariate adjustment in randomized controlled trials with dichotomous outcomes increases statistical power and reduces sample size requirements. *J Clin Epidemiol.* 2004;57(5):454-460.
89. Centers for Disease Control and Prevention, National Center for Health Statistics: Vital and Health Statistics. *Table 57. Participation in leisure-time aerobic and muscle-strengthening activities that meet the federal 2008 Physical Activity Guidelines for Americans among adults aged 18 and over, by selected characteristics: United States, selected years 1998–2016.* 2017.
90. Kubo A, Kurtovich E, Aghaee S, Nkemere L, Avalos LA. mHealth mindfulness intervention for women with perinatal depression: a pilot study within an integrated health care system Paper presented at: 8th World Congress of International Association for Women's Mental Health (IAWMH); Mar 5 - 8, 2019 2019; Paris, France.
91. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* Hillsdale, New Jersey: Lawrence Erlbaum Associates; 1988.
92. Statista. Number of smartphone users in the U.S. from 2010 to 2018 (in millions). 2015; http://www.statista.com/statistics/201182/forecast-of-smartphone-users-in-the-us/. Accessed March 18, 2015, 2015.
93. Kaiser Family Foundation. Mental Health Care Health Professional Shortage Areas (HPSAs). In: Kasier Family Foundation; 2018.

b. Preliminary Data

Describe any relevant preliminary data.

Strong evidence suggests physical activity (PA) can reduce depression risk by half.[18-22] While national guidelines and professional organizations, including the American College of Obstetricians and Gynecologists, recommend at least 150 minutes per week of moderate to vigorous intensity PA for postpartum women,[23,24] 70% of postpartum women do not meet these guidelines.[25-30] Technology-based (eHealth) interventions have been shown to effectively increase PA in the general population.[31,32] Few eHealth PA interventions are available specifically for postpartum women, but a recent eHealth program (MomZing) has been successful in increasing PA to more than three times baseline levels in this population.[33] While the MomZing study found lower depressive symptoms in women who met national PA guidelines after 3 months of intervention, no eHealth PA interventions (including MomZing) have been tested in women at increased risk of PPD, a population that may need additional motivation and social support. Social support is the strongest contributor to PA behavior change in postpartum women.[34] The proposed eHealth PA intervention (MomZing) is an intervention that targets each of the three components necessary for behavior change according to the COM-B model: "**C**apability" (e.g., knowledge and skills), "**O**pportunity" (e.g., time), and "**M**otivation" to engage in PA **B**ehavior change.[35-37]

4. Study Design

Describe the overall approach of the study (e.g. prospective, interventional, observational, retrospective, etc.). If your study includes more than one group, arm, or subject population, describe that here (for example, a study of both subjects and their caregivers, or a study with both a prospective interventional arm and a retrospective chart review arm).

This is a hybrid effectiveness-implementation study including 1) a randomized controlled trial to test the effectiveness of MomZing to increase PA and reduce postpartum depressive symptoms in women at increased risk of PPD and 2) evaluation of implementation of MomZing within the KPNC health care delivery system.

Assess whether this study involves a clinical trial. Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Yes, this study involves a clinical trial. It is a randomized control trial of a behavioral intervention where participants will be randomized into 1 of 2 arms: (1) MomZing (intervention, n=100) or (2) Usual care (control, n=100).

Describe whether the study involves educational tests, survey procedures, or interview procedures.

Yes, the study involves surveys. All eligible women will be asked to 1) complete a baseline survey which includes self-report of PA and 2) wear a research-grade accelerometer for 7 days to assess baseline PA. Women will then be randomized into 1 of 2 arms: (1) MomZing (intervention, n=100) or (2) Usual care (control, n=100). They will complete surveys again at 3 months (T1) and 6 months (T2) after baseline. There will be one final survey when the participant's child is approximately 12 months old to assess child development. Depending on the age of the infant at enrollment, this may occur at T2.

We will conduct key stakeholder interviews with clinicians and clinical leaders, identified through the OBGYN Peripartum Depression Champions Committee, which consists of a depression champion clinician from different KPNC facilities, to address and identify avenues for *adoption* of MomZing and barriers to *implementation* and *maintenance* within clinical practice at KPNC.

Describe whether the research involves benign behavioral interventions on **adult** subjects. Note: Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and not offensive or embarrassing to the subjects. Examples include having subjects play online games or solving puzzles under various noise conditions.

As described above, all eligible women will be asked to wear a research-grade accelerometer for 7 days to assess baseline PA and then randomized into MomZing (intervention) or Usual care (control). They will wear the accelerometer again for 7 days at 3 months post-baseline and 6 months post-baseline.

MomZing intervention: the MomZing online exercise application (www.momzing.com) was developed based on mothers' preferences for exercise videos that: 1) instructed mothers how to

exercise safely with their baby based on the infant's weight and developmental stage; 2) did not require exercise equipment or a substantial time commitment per video (e.g., maximum time per video 10 minutes); 3) provided different types of physical activities (e.g., yoga, strengthening, cardio) and intensity levels (light, moderate, hard); and finally, 4) featured women in the exercise demonstrations who were "real" mothers (not fitness instructors) exercising with their own infant. Users can either select up to three 10-minute videos to create a 10 to 30-minute workout or choose a 'Ready Made' workout that is either 10, 20, or 30-minutes long.

If the study involves either educational tests, survey procedures, interview procedures, or benign behavioral interventions **(on adults)**, specify whether one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects

N/A

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

N/A

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination

Confirmed.

5. Study Population

a. Number of Subjects

State the number of subjects you plan to include at the KP region to which this study is being submitted. If applicable, distinguish between the number of subjects who are expected to be enrolled/screened and the number of subjects needed to complete the research procedures (e.g. number of subjects excluding screen failures).

We will identify approximately 132,000 postpartum women at the KPNC region for potential participation using electronic health records data, including their depression screening at their 4-6 weeks postpartum visit received as part of the KP universal perinatal depression screen program, to assess eligibility.

To pilot test the implementation of the intervention and maximize the recruitment rate over the study period we will identify and recruit women through two methods: 1) Clinician referrals and 2) EHR identification. We will randomize 200 women into 1 of 2 arms: 1) Intervention (MomZing, n=100) or 2) Control (Usual care, n=100) using a restricted randomization scheme to ensure an acceptable level of between-arm balance in the distribution of important covariates (e.g. KP clinic, race/ethnicity, age, parity, marital status, and education).

We will also include the children of participants in the study by accessing and linking records for each enrolled mother/baby to extract data regarding the pregnancy and other health factors including child development and behavioral problems, maternal-infant interaction, and breastfeeding.

To evaluate procedures for implementation of MomZing at KPNC, we will conduct qualitative interviews with approximately 20 clinicians and clinical leaders, identified through the OBGYN Peripartum Depression Champions Committee.

As appropriate, differentiate between different populations of subjects within the same study (e.g. subject/caregiver, parent/child, patient/physician).

Aim 1: This is a study of patients (mothers and their infants). We are specifically interested in postpartum women at increased risk of PPD.

Aim 2: The study includes clinical staff and leadership identified through the OBGYN Peripartum Depression Champions Committee, which consists of a depression champion clinician from different KPNC facilities.

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

N/A

b. Inclusion and Exclusion Criteria

- Describe the criteria that define who will be included or excluded in your final study sample.

  Aim 1: The final study sample will include 200 women randomized into 1 of 2 arms: Intervention (MomZing, n=100) or Control (Usual Care, n=100).

  Women will be considered eligible if they:

- Are English-speaking and between the ages of 18 and 45
- Had prenatal care at KPNC and delivered their child at a KPNC hospital
- Are at increased risk of PPD between 2 and 6 months postpartum[a]
- Own a smartphone, computer, or TV with internet access
- Do not have a depression diagnosis or receive any treatment for depression (e.g. taken antidepressant medications or received psychotherapy)
- Are free of a heart condition and a physician recommending medically supervised physical activity
- Do not have chest pain during physical activity, or developed chest pain within the prior month
- Do not take medication for hypertension or a heart condition
- Have no tendency to fall due to syncope or dizziness
- Have no orthopedic problems that might be aggravated by physical activity
- Do not have exercise-induced asthma
- Are not pregnant or planning to become pregnant in the ensuing three months

- Have a Body Mass Index (BMI) between 18.5 and 40 (kg/m^2)
- Are not engaging in regular, moderate-to-vigorous physical activity >30 minutes per week

and if their infants[b]:

- Are between 2 and 6 months old
- Weigh between 11-22 pounds
- Are free of chronic illness/disorder that prevents someone from holding or lifting them

[a]Women will be considered at increased risk for PPD if they do not have a current depression diagnosis defined as a diagnosis between delivery and the time of the PHQ-9 score but have a PHQ-9 score between 10-19. Women who have a PHQ-2 score of ≥3, administered at well-baby visits, will also be considered at increased risk.
[b]The mothers in the intervention will be instructed how to safely exercise based on the infants' weight and developmental stage.

Aim 2: All clinicians and clinical leaders who are identified through the OBGYN Peripartum Depression Champions Committee, which consists of a depression champion clinician from different KPNC facilities, will be eligible to participate in the qualitative interviews.

- Describe how individuals will be screened for eligibility.

Please see above for eligibility requirements.

Aim 1: We will identify and recruit women through two methods: 1) Clinician referrals and 2) EHR identification. Clinician referrals: we will work closely with the OBGYN Peripartum Depression Champions at all KPNC clinics to encourage clinicians at their clinics to refer to the study. Clinical staff will be asked to refer potential participants to the study by briefly describing the study and providing the study brochure (hard copy if postpartum visit is in-person and electronically if visit is virtual), which includes the study contact information, then notify the study team to follow-up with referred patients.

EHR identification: we will routinely identify eligible women from the EHR at all clinics throughout KPNC and obtain provider approval to contact his/her patient.

Aim 2: There will be no screening for eligibility. All clinicians and clinical leaders who are identified through the OBGYN Peripartum Depression Champions Committee, which consists of a depression champion clinician from different KPNC facilities, will be eligible to participate in the qualitative interviews.

- If information or biospecimens will be obtained for the purpose of screening, recruiting, or determining eligibility, informed consent is not required if one of the following criteria is met. Select one of the following criteria and provide a brief explain for how the criteria is met.

  - ☐ The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

X The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

For the purpose of screening, recruiting, and determining eligibility, we will need to access PHI to identify postpartum women, who are screened for depression at their postpartum visit, and clinicians. It is necessary to access PHI to assemble the cohort, obtain all the study specific variables and link the data for this study. Without access to and use of the necessary PHI the research cannot be conducted.

IMPORTANT NOTES: Although informed consent may not be required, HIPAA Privacy Authorization may still be required. Also, if this study is FDA-regulated, then consent may be required.

- Describe the plan for disposition of information/biospecimens collected during recruitment/screening in the event of a screen failure or when a potential subject is contacted but declines participation (e.g. destroyed immediately, destroyed at end of study, retained for separate analysis or so that subjects are not contacted repeatedly about participation after they have declined, etc.).

Data collected during recruitment/screening or when a potential subject is contacted for participation but declines will be destroyed at the end of the study. Subjects will not be contacted about participation after they have declined.

Non-respondent data will be used in the study. Any collected data will be destroyed at the end of the study.

For those who decline to have their data be used for this study, any collected data will be destroyed at the end of the study.

c. Subjects Vulnerable to Coercion or Undue Influence

Indicate whether you will include or exclude each of the following special populations. Justify the inclusion of any of these populations. Describe additional safeguards to protect the rights and welfare of these subjects. Note: This refers to subjects who are known members of these populations upon enrollment or at any time during the study.

- Children

We will include children in the proposed study. We will need to access and link records for each enrolled mother/baby to extract data regarding the pregnancy and other health factors including child development and behavioral problems, maternal-infant interaction, and breastfeeding for 3 reasons: 1) inclusion/exclusion criteria (i.e. we cannot recruit women with infants that have a chronic illness and thus need to access their medical records), 2) to assess the relationships as outlined in the Aims, and 3) monitor adverse events and safety outcomes (e.g. identify any injuries that may have been treated by a doctor or required hospitalization and follow-up and their relationship with the intervention).

Only persons directly involved in the study will have access to the data identifying individual participants. Names of participants will be obtained for record-keeping purposes

only; no names will be recorded in the data analysis files. No individuals will be identified in the results of the studies. Access to computer-stored information will require simultaneous knowledge of the data format, computer language, file name, and password.

- Neonates of uncertain viability or nonviable neonates (up to 28 days post birth)

  N/A

- Prisoners (NOTE: The KP IRB does not have the appropriate membership to review research involving prisoners. Consultation with the IRB Office will be required.)

IMPORTANT NOTE: Consider whether subjects will be in a vulnerable category at the time of information/biospecimen collection or during analysis. For instance, if you collect information/biospecimens about children who were ages 12 – 15 from years 2000 – 2002, you know that now those individuals are no longer children.

Individuals with Impaired Decision-Making Capacity

State whether individuals with impaired decision-making capacity will be included.

N/A

Explain the extent of cognitive impairment (complete, fluctuating, progressive, or temporary).

N/A

Justify their inclusion and explain any protections to mitigate risk (such as the involvement of a caregiver or legally authorized representative).

N/A

Describe the process to determine whether an individual is capable of consent, and submit any documents that will be used assess decisional capacity.

N/A

List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.

N/A

Describe the process for assent of the subjects by addressing the following:

- Whether assent will be required of all, some, or none of the subjects. If assent will be obtained from some subjects, indicate which subjects will be required to assent and which will not.

  N/A

- If assent will not be obtained from some or all subjects, an explanation of why not.

N/A

- When assent is obtained, describe how it will be documented.

N/A

HIV Status:

If the study will be ascertaining subject HIV status for study exclusion/inclusion, please indicate how:

☐ Prospective laboratory HIV testing of subjects for the study

☐ Surveying subjects about their HIV status

☐ KPNC HIV Registry access or existing electronic health record data*

*If you checked this option, you must first gain approval from the HIV Steering Committee by contacting Michael J. Silverberg, PhD, MPH. The HIV Steering Committee approval must be submitted to IRBNet.

Will TPMG physicians be directly contacted to enroll as study participants? ☒ **Yes** ☐ **No**

If "yes" the contact must be approved by Yi Fen Irene Chen, MD, Associate Executive Director, TPMG, prior to IRB review. Dr. Chen's approval must be submitted to IRBNet.

Other Populations Targeted for Recruitment
If you are targeting a population that may be vulnerable to coercion or undue influence based on the specific circumstances of the study, describe how you will ensure that participation is voluntary and minimize any added risk. (Common examples include employees, students, economically or educationally disadvantaged persons, etc.)

N/A

d. Setting
Describe the sites or locations where your research team will conduct the research.

This project will take place at the Division of Research.

If this is a multi-site study:

- Specify what procedures are being performed at this site or by this site's personnel (consider recruitment, consent process, study procedures, information/biospecimen analysis, etc.).

N/A

- State how each site will satisfy its IRB review requirements. Indicate if you are asking this site's IRB to rely on another IRB or if another institution would like to rely on this site's IRB and include this information in the eIRB Initial Project submission

N/A

For research conducted outside this site describe: (Community, Reservations etc.)

- Describe site-specific regulations or customs affecting the research at that location.

N/A

- Local scientific and ethical review structure outside this site.

N/A

6. Recruitment Methods

Describe how study participants will be recruited and enrolled.

Aim 1: We will identify and recruit women through two methods: 1) Clinician referrals and 2) EHR identification.

Clinician referrals: we will work closely with the OBGYN Peripartum Depression Champions at KPNC clinics. Clinical staff will be asked to refer potential participants to the study by briefly describing the study and providing the study brochure (hard copy if postpartum visit is in-person and electronically if visit is virtual), which includes the study contact information, then notify the study team to follow-up with referred patients.

EHR identification: we will routinely identify eligible women from the EHR at all clinics throughout KPNC and obtain provider approval to contact their patient. If the provider does not respond to our request, we will wait 14 days to contact the woman.

Using the study email (POW-Study@kp.org), a KP Outlook account, we will send referred and identified women an email requesting their participation. The email will include the baseline survey link. Each woman will also need to provide her own unique credentials (date of birth), thus authenticating her own identity. After logging in and answering a few eligibility questions, she may choose to refuse participation ("No" response) or to participate ("Yes" response) in the study. If she participates, she will complete the consent before proceeding to the baseline survey via REDcap. We will follow-up with women, by phone, who do not respond or complete the survey in a timely manner. Please see the clinician referral script, study brochure, sample participant recruitment email after clinician referral, sample provider email, sample participant recruitment email, and telephone script (Appendices A-F).

Also, see the sample follow-up email (Appendix G) sent to participants with the survey link if they are recruited by phone via Appendix F.

Aim 2: For the clinician interviews, the Principal Investigator (Dr. Lyndsay Avalos) with Co-Investigator (Dr. Mibhali Bhalala) will send an email, to OBGYNs and OBGYN Peripartum Depression Champions informing them of the study and asking for their participation. If they are interested in participating, we will call and set up a time for an interview, which will be recorded and conducted in-person, by telephone or video (via Microsoft Teams), whichever is more convenient for them. Interview recordings will be destroyed at the end of the study. We are requesting a waiver of the requirement to obtain written consent for the interviews, and instead

propose a study information sheet and verbal consent. Please see the recruitment email to clinicians and telephone script (Appendices Q and T).

Indicate whether you will openly recruit using advertisements, websites, flyer, or brochures. (Upload the final versions of all recruitment materials to your submission to the IRB.)

Aim 1: We will use a study brochure that will be provided to KPNC clinics so they may refer any potential participants to the study. Please see Appendix B. All recruitment materials will also refer participants to our study website should they have any questions and need additional information. The website will be hosted internally by DOR IT and used as an informative tool rather than a means to openly recruit.

Indicate if you plan to do targeted recruitment using existing records or referral. Please submit final versions of all referral emails/scripts.
Please see above.

Describe, by position/title, who will be recruiting and enrolling participants (providing the specific names of research team members is not necessary).

Aim 1: A research assistant will be recruiting and enrolling patient participants. She will send the initial recruitment email and follow-up with those who do not respond in a timely manner. She will also follow-up with enrolled participants reminding them to wear their accelerometers and complete follow-up surveys throughout the study period.

Aim 2: The Principal Investigator (Dr. Lyndsay Avalos) with Co-Investigator (Dr. Mibhali Bhalala) will send the provider recruitment email to the clinicians. Dr. Bhalala is the Peripartum Depression Champion at the Redwood City OB clinic. The research assistant and Co-PIs will follow-up, i.e. sending email reminders, answering questions, etc. from thereon, using the study email.

Describe any plans for the participants in the currently proposed study to be re-contacted or recruited for future follow-up studies. (Note that participants should be informed of this potential for re-recruitment or future follow-up studies during the current study's consent process.)

There are currently no plans for any future follow-up studies however, during the consent process, participants will be asked to specify whether they are interested in being contacted to learn about future studies.

Please note the following KPNC IRB guidelines:

- Contact of prospective subjects will be limited to three (3) attempts in one week, for no longer than three (3) continuous weeks.
- Messages left will be limited to one (1) per week for no more than three (3) weeks.
- No more than two (2) recruitment mailings (email, flyer, brochure, etc.).
- If permission from the patient's PCP is necessary to contact the patient:
  - If PCP does not respond to request, recruitment attempts (phone, mailings, etc.) may not begin until 2 weeks after the PCP's permission was requested.
  - If PCP grants permission, recruitment attempts may begin with no waiting period.

7. Informed Consent Process
   a. Written Consent

Describe how you will obtain and document consent, including:

- Where, when and how the consent process will take place.

Aim 1: Once an eligible woman agrees to participate, she will access the consent and HIPAA form in REDcap before proceeding to the survey via the link provided to her. She will not be able to complete the survey until consent is obtained first. If participants have technical issues navigating the consent or questions about the consent form itself, they may contact the study team by phone or email. Upon providing consent, which will be documented by signing with a stylus electronically, participants will be issued a signed copy of the consent form. Please see informed consent (Appendix H).

- How the research team will ensure that subjects have sufficient time to consider whether to participate in the research

Aim 1: For participants who are referred to the study by their clinicians, they will have already learned about the study and discussed participation giving them ample time to consider whether they would like to participate. The research assistant will also follow-up by phone with women who need time to consider participation, those who do not respond to the email, and those who initially agree but do not complete the survey in a timely manner.

- A process to ensure ongoing consent.

Consent will be obtained before the baseline survey. Participants will be informed that their participation in the study is completely voluntary and that they are free to refuse to participate in the study. They may also withdraw from the study once enrolled. We will not be consenting again before the subsequent surveys.

- Steps that will be taken to minimize the possibility of coercion or undue influence.

By sending the participants an email with link that requires their unique credentials (date of birth) to login and because participants will not be able to complete the survey until consent is obtained first, this ensures that they have had time to read the consent and understand their roles and rights as participants. They will participate under their own discretion minimizing any possibility of coercion or undue influence.

- Any steps that will be taken to ensure the subjects' understanding.

Study contact information (study line and email) will be provided during recruitment and in the consent if participants have any questions before deciding to participate. The research assistant will also follow-up with women who need time to consider participation, those who do not respond to the email, and those who initially agree but do not complete the survey in a timely manner.

NOTE: For each federally-supported clinical trial, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or sponsor conducting the trial on a publicly available Federal website that will be established as a repository for such informed consent forms.

b. Waiver of Informed Consent

Provide rationale and justification for the Waiver of Informed Consent for this study, including:

- Explain how the proposed research presents no more than minimal risk to the study participants.

  We are requesting a waiver of informed consent for the purpose of eligibility screening. We will collect information from potential participants to determine eligibility presenting no more than minimal risk to these potential participants since it involves answering a few questions and no other procedures for which written consent is normally required outside of the research context. The risk is also vigorously protected through our data protection methodology.

- Explain how the waiver of informed consent will not adversely affect the rights and welfare of the participants.

  Eligibility screening has no direct correlation to the care of any participants. The collected information will be strictly protected and will not be disclosed to any party not involved in the study. There should be no adverse impact on the rights and welfare of the participants as the only risk is a breach of confidentiality.

- Explain why this research cannot practically be carried out without a waiver of informed consent. Note: research regulations require that justification for a waiver of consent explain why it is impracticable to perform the research, and not just impracticable to obtain consent. Practicability cannot be determined solely by considerations of convenience/cost/speed.

  It would not be feasible to contact each participant to obtain consent to screen for eligibility as we will need to use the collected information to compare participants to non-participants to demonstrate that our sample is not biased, and the study results are generalizable. Thus, it would be impracticable to conduct the research without a waiver of informed consent for eligibility screening.

- If the research involves using identifiable private information or identifiable biospecimens, provide justification for why the research cannot practicably be carried out using deidentified information.

  It is not practicable to only use deidentified information because we need to retain identifiers in order to link important sources of data for analysis. We also could not examine patient outcomes over time if we deidentified the data.

- Assess whether it is appropriate to provide the subjects with additional pertinent information after participation.

It would not be appropriate to provide the subjects with additional information after participation given some may not be eligible to participate once they are screened.

c. Waiver of Signed (Documented) Informed Consent

Provide rationale and justification for the Waiver of Signed (Documented) Informed Consent by identifying which of these three conditions applies and justification for how the criteria is met.

1) The research involves no more than minimal risk to participants AND involves no procedures for which written consent is normally required outside of the research context.

Aim 2: For the clinicians, the recruitment email will include the study information sheet. We propose waivers of the requirement to obtain written consent since there is no more than minimal risk to them and involves no procedures beyond an in-depth interview to address identified avenues for *adoption* of MomZing and barriers to *implementation* and *maintenance* within clinical practice at KPNC. Please see the study information sheet (Appendix R).

2) The signed consent form would be the only record linking the participants to the research, and the principal risk to participants would be potential harm resulting from a breach of confidentiality.

Click or tap here to enter text.

3) The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm.
   a. Describe the distinct cultural group or community
   b. Describe why signing forms is not the norm
   c. Explain how the research presents no more than minimal risk of harm to these subjects
   d. Provide an appropriate alternative mechanism for documenting that informed consent is obtained

Click or tap here to enter text.

d. Alteration of Informed Consent

Identify the required elements of informed consent that you wish to remove or alter.

N/A

Provide justification for their removal or alteration.

Click or tap here to enter text.

e. Non-English-Speaking Subjects

If subjects who do not speak English will be enrolled, describe how the consent discussion will take place and indicate if translated consent forms or short forms will be used. Confirm that an interpreter will assist with the initial consent process and subsequent study visits.

N/A

IMPORTANT NOTE: Please be aware that if it is expected that you will enroll non-English speakers in the study, short forms should not be used as the only Consent option for these individuals, they should only be used if a non-English speaking participant is unexpectedly encountered. However, the possibility of encountering non-English speaking potential subjects in the Bay Area is a possibility and this possibility should be considered, and budgeted for, when preparing the initial study submission for IRB review.

f. Assent of Children and Parent Permission

IMPORTANT NOTE: Child Consent may be obtained in certain situations (for example, conducting family planning or sexually transmitted disease (STD) research). In addition, for older children ages 16 and up who participate in an adult study, the consent document can be used in place of the assent document.

Describe how you will obtain and document assent/parental permission, including:

- Describe your plan for obtaining parent permission. The permission of one parent is generally sufficient for minimal risk research, or for greater than minimal risk research if there is the potential for direct benefit to the child. For studies involving greater than minimal risk with no prospect of direct benefit to the child, permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Aim 1: Parent permission will be obtained for accessing child records and child assent will not be obtained.

- Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission.

  N/A

- Indicate whether assent will be obtained and documented from all, some, or none of the children.

  Aim 1: Assent will not be obtained from any of the children.

- If assent will only be obtained from some children (because of very young age, severe cognitive impairment, etc.), indicate which children will be required to assent and which will not.

  N/A

- When assent of children is obtained, describe whether and how it will be documented.

  N/A

- When subjects might reach the age of majority during the study, describe the plan to obtain consent from these subjects at that time using an adult consent form.

  N/A

g. Secondary Research for Which Consent is Not Required:
Note: Research involving the use of identifiable biospecimens does not apply to this section.
Note: Although consent may not be required, justification for a waiver of HIPAA Privacy Authorization may still be required.

Secondary Research of identifiable private information or identifiable biospecimens may not require informed consent if at least one of the criteria listed below is met. Select at least one of the following criteria and provide a rationale for how the criteria is met:

- Use of publicly available identifiable private information or identifiable biospecimens.

  N/A

- The information and/or biospecimens are recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.

  N/A

- The research involves only information collection (i.e. no biospecimen collection) and the analysis of this identifiable health information is regulated by HIPAA.

Aim 1: We will use non-respondent data in two ways. First, we will compare participants to non-responders on demographic characteristics and other factors such as medical conditions (e.g, chronic conditions, mental health conditions, etc.) and pregnancy behaviors (e.g. substance use) available in the EHR to demonstrate external validity (e.g. that our sample is not biased and the study results are generalizable).

Aim 2: Non-respondent data will be used to assess implementation of the intervention into the health care system and will require demographic and health data as described above for all eligible women. As such, the research involves only information collected and the analysis of this identifiable health information is regulated by HIPAA.

8. HIPAA Privacy Rule Authorization

a. Written HIPAA Privacy Rule Authorization:
Describe the plan to obtain a signed Privacy Rule Authorization from each subject.

We will obtain a signed Privacy Rule Authorization from each enrolled subject upon providing consent. Please see Appendix I.

b. Waiver of HIPAA Privacy Rule Authorization
If you will not obtain a signed HIPAA Privacy Rule Authorization or if you want to eliminate any required language from the authorization, provide the following rationale and justification.

- Explain why the research could not practicably be conducted without the waiver. Note: research regulations require that justification for a waiver of HIPAA Authorization explain why it is impracticable to perform the *research*, and not just impracticable to obtain HIPAA Authorization. Practicability cannot be determined solely by considerations of convenience/cost/speed.

  Aim 1: We are requesting a waiver of the requirement for a signed authorization for the purpose of identifying potential participants for recruitment. We need to access PHI to identify postpartum patients as well as clinicians to conduct interviews. The clinician recruitment emails will include a study information sheet as well. Because the research involves no more than minimal risk to clinicians and involves no procedures for which written consent is normally required outside of the research context, it would be impracticable to obtain the signed authorization.

  We are also requesting a waiver of the requirement for a signed authorization for non-respondent data. We need to access non-respondent data to compare participants to non-responders on demographic characteristics and other factors such as medical conditions and pregnancy behaviors available in the EHR to demonstrate that our sample is not biased and the study results are generalizable.

  Aim 2: Additionally, to assess implementation of the intervention into the health care system requires demographic and health data as described above for all eligible women. As such, without a waiver of authorization, it would not be feasible to identify and assemble these cohorts or conduct secondary analysis.

- Explain why access to and use of the PHI is necessary for the research.

  We need to access PHI to identify postpartum patients and clinicians and conduct secondary analysis. It is necessary to access PHI to assemble the cohort, obtain all the study specific variables and link the data for this study. Without access to and use of the necessary PHI the research cannot be conducted.

- Explain why the use or disclosure of PHI for the research poses no more than minimal risk to the subjects' privacy.

  We will need to access PHI only for the purpose of identifying potential participants for recruitment and conducting secondary analysis. The research involves no more than minimal risk to participants AND involves no procedures for which written consent is normally required outside of the research context.

- Provide an adequate plan to protect the PHI from improper use or disclosure.

  Any data with identifiable information will be password protected by the programmer. An additional dataset will be created and used by the programmer which will not include any PHI. We will provide assurance of the confidentiality and proper procedures for protecting PHI as set forth by the KPNC IRB.

- Provide a plan to destroy identifiers at the earliest opportunity consistent with the purpose of the research.

Personal identifiers will be destroyed at the end of study according to IRB requirements.

c. **HIPAA Disclosure Accounting**

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule gives patients the right to receive a listing, known as an accounting of disclosure, of their information that is disclosed to others for reasons other than treatment, payment, or health care operations. KP must account for all known disclosures of protected health information for research purposes without the individual's authorization (a waiver or alteration of HIPAA Authorization) both within a KP region (between a Permanente Medical Group, Kaiser Foundation Hospitals, and a Kaiser Foundation Health Plan) and outside of KP.

- What type of PHI is being disclosed?
  ☒ Clinical/Diagnostic
  ☒ Demographics
  ☒ Healthcare

- How many participants are expected to be enrolled in this study at your region?
  ☐ 49 or less individuals

  The investigator should maintain an individual accounting record of all Disclosures made by the research team that are subject to the HIPAA tracking requirements. The investigator must also transmit this tracking information within 20 days of Disclosure to the Regional Compliance Officer. Using: Health Connect Quick Disclosure or Complete the Disclosure of PHI about a single individual for a research purpose Form.

  ☒ 50 or more individuals

  If 50 or more individuals, please provide the information for each entity that sponsored the research where PHI is being disclosed. *Please note: If you are disclosing PHI to more than one entity, the following is needed for each entity.*

  - **Name**
    Between employees of The Permanente Medical Group and KP NCAL Kaiser Foundation Health Plan/Hospital employees (for this project research team members are either TPMG or KP NCAL KFH/HP employees)

  - **Address**
    KP NCAL Region

  - **Phone Number**
    Division of Research 510-891-3400
    KP Redwood City 650-299-2000

If disclosing PHI to more than one entity, please continue entering the required information below:
N/A

9. Study Procedures

a. Description

Describe and explain the study design, including:

- A detailed chronological description of all research procedures.

This is a hybrid effectiveness-implementation study including 1) a randomized controlled trial to test the effectiveness of MomZing to increase physical activity and reduce postpartum depressive symptoms in women at increased risk of PPD and 2) evaluation of implementation of MomZing within the KPNC health care delivery system. We will identify potential participants and assess them through clinician referrals and using KPNC's electronic health records data for eligibility. All eligible and recruited women will complete a baseline survey including self-report of PA and wear a research-grade accelerometer for 7 continuous days to assess baseline PA. We will mail the accelerometer and wearing instructions, and also provide a self-addressed prepaid postage envelope for participants to return the items after each measurement period. All participants will be informed that they do not have to answer any question in the surveys they do not wish to answer. We will then randomize 200 women into 1 of 2 arms: 1) Intervention (MomZing, n=100) or 2) Control (Usual care, n=100) using a restricted randomization scheme to ensure an acceptable level of between-arm balance in the distribution of important covariates (e.g. KP clinic, race/ethnicity, age, parity, marital status, and education). The nature of the group assignment and intervention does not allow for blinding of the treatment conditions from the participant or the research assistant whose task is to register and explain the use of the MomZing intervention. The programmer/analyst, biostatistician, and investigators will be blinded to the study arms. Once randomized, participants will begin their assigned group's intervention or control treatment for 3 months. We will obtain both self-report and accelerometer-measured PA and depressive symptoms at 3 months (T1) and 6 months (T2) post-baseline for each woman in their respective arms. There will be one final survey when the participant's child is 12 months old to assess child development. Non-respondent data will be used for those who do not respond to the recruitment emails and calls. They will be given 30 days to opt out of the study and informed that their data may be used if they do not respond.

MomZing Intervention – Women in this arm will participate in the online fitness program, including setting physical activity goals, tracking their workouts using the built-in workout tracker on the MomZing website, and playing the exercise videos.

Control (Usual care) – Participants in this arm will receive usual postpartum care for women at increased risk of depression, which is currently a brief discussion about their depression symptoms.

To evaluate procedures for implementation of MomZing at KPNC, we will conduct recorded qualitative interviews with clinicians and clinical leaders to help identify a sample of approximately 20 clinicians. Interview recordings will be destroyed at the end of the study.

- Procedures to monitor subjects for safety, including who will review the data and at what frequency for safety issues.

  The study team, specifically the project manager, programmer, and research assistant will monitor subjects for safety and assist participants when navigating the surveys and MomZing website, if needed. They will also review adverse event data every 6 months during the data collection period to assess any potential safety issues. The research assistant will also ensure participants, especially at baseline, are properly wearing the accelerometer and answer any questions. Should any issues arise, they will address them, accordingly, including consulting with the PI and Co-Is. The PIs will review all safety data collected at the 3-month (T1) and 6-month (T2) follow-up surveys every 6 months during data collection.

- Procedures performed to lessen the probability or magnitude of risks.

  To lessen the probability or magnitude of risks, only the study email address will be used to send and receive participant email. Also, the survey link that will be sent is unique for each participant and thus will minimize any risks as well. Lastly, participants will need to provide their own credentials (date of birth) to authenticate their identities before starting the survey.

- The source records that will be used to collect information about subjects. (Attach all surveys, scripts, and data collection forms.)

  Please see the four surveys (baseline, 3 months post-baseline, 6 months post-baseline, and ASQ-3 infant 12-month survey) that will be conducted via REDcap for patient participants (Appendices M-P) and the interview guide for the clinician interviews (Appendix S).

- What information and/or biospecimens will be collected including during long-term follow-up.
  Please note, if biospecimens being collected are being used to develop an investigational in vitro diagnostic device, an IDE for the device may be needed. Please review the IVD Device FAQs in IRBNet for guidance.

  Data Sources: Data used in this study will be from a combination of EHR databases, surveys, accelerometers, and the MomZing website. We will conduct surveys via REDcap and accelerometer-measured PA data collection at 3 timepoints: a) baseline (T0, before intervention), b) 3 months post-baseline (T1), and c) 6 months post-baseline (T2). There will be one final survey to assess 12-month child development as well. Lastly, we will conduct qualitative interviews with key stakeholders to evaluate procedures for implementation.

  Measures:
  Demographic characteristics and health information. Information on mom and baby with regards to race/ethnicity, age, education, income, marital status, parity, substance use,

general health, health behaviors, health care utilization will be ascertained from a combination of KPNC EHR databases and the online surveys.

Outcomes

Physical Activity. PA will be measured using accelerometry (Actigraph wGT3X-BT physical activity monitor) and self-report (sports/exercise domain of the Pregnancy Physical Activity Questionnaire) at T0, T1, and T2.

Depression and Depressive symptoms. Depressive symptoms will be measured at recruitment, T1, and T2 using the Patient Health Questionnaire (PHQ-8) and assessed as a continuous outcome. The 8-item, PHQ-8 depression screener is a validated instrument adapted from the PHQ-9. The PHQ-8 excludes the question regarding suicidal thoughts. PHQ-8 scores range from 0-24. A score of 1-4 suggests minimal depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression and 20-24 severe depression. Depression diagnoses will be ascertained from the EHR.

Anxiety and Anxiety symptoms. Anxiety symptoms will be evaluated using the Generalized Anxiety Disorder 7-Item Scale (GAD-7), a self-rated assessment developed to screen for general anxiety disorder. Anxiety diagnoses will be ascertained form the EHR.

Adherence. The MomZing website automatically records adherence data (time, type, date, duration of exercise video) for each participant. Quarterly usage reports for participants in the intervention will be generated and sent to us by Klein Buendel.

Additional outcomes measures included in the survey: sleep, patient satisfaction, self-efficacy, social support for and barriers to PA, the impact of COVID-19 on pregnancy, substance use measures, and infant development.

Implementation evaluation measures. Process measures and key stakeholder interviews will be used to assess the Reach, Effectiveness, Adoption, Implementation, and Maintenance components of the RE-AIM framework.[68] *Reach* of the intervention will be evaluated using the participation rate among contacted eligible participants and comparison of characteristics available in the EHR between participants and eligible non-participants. *Effectiveness* will be measured through the results of the randomized controlled trial, by examining the data for a dose-response association between intervention engagement/adherence (number of exercise videos viewed), PA, and depressive symptoms, and through participant satisfaction with the intervention. Satisfaction will be assessed as part of the T1 online surveys. *Adoption* will be assessed by calculating personnel costs associated with the intervention (e.g. clinic referral staff). Additionally, key stakeholder interviews with clinicians and clinical leaders will address identified avenues for *adoption* of MomZing and barriers to *implementation* and *maintenance* within clinical practice at KPNC. The standard criteria for generating a RE-AIM public health impact score will be followed.[68]

- The duration of an individual subject's participation in the study.

For the patient participants, participation will begin between 2 and 6 months postpartum (baseline), depending when they are recruited, and will conclude after the women complete the final survey when their child is 12 months old.

For the clinicians, participation is complete after the one-time interview to identify barriers and addressing implementation and evaluate potential adoption of MomZing.

- The duration anticipated to enroll all study subjects.

The anticipated duration to enroll all study subjects will be from 08/01/2020-03/31/2022.

	Year 1				Year 2				Year 3			
IRB approval		M										
MomZing development/final product		D									D	
Clinic implementation workflow/protocol		D									D	
Participant recruitment									M			
Data collection											M	
Stakeholder interviews		M									M	
Data analysis												M
MomZing effectiveness manuscript												D
Implementation findings report												D

M=milestone, D=deliverable

- The estimated date for the investigators to complete this study (complete primary analyses) NOTE: It should be clear exactly which procedures will be conducted for the research as opposed to procedures the subjects would undergo (in the exact manner described in the protocol) even if they were not participating in the study.

The estimated date will be 12/31/2022.

- Describe procedures that will be followed when subjects withdraw from the research, including withdrawal from intervention but continued information and/or biospecimen collection.

During recruitment, participants will be informed that their participation in the study is completely voluntary and that they are free to refuse to participate in the study. Their decision whether or not to participate in the study will not affect their medical care. If they decide to participate, they are free to change their mind and discontinue participation at any time without any effect on their medical care or eligibility for future care or membership in KFHP. At any time during the study, if participants no longer want to participate or have their information used as part of the study, they must write a letter stating that they withdraw their participation and authorization and send it to the PI, Dr. Lyndsay Avalos, at which time we would remove her from the study. We will use any PHI obtained for this study before they withdraw their authorization but will not use any PHI obtained after their withdrawal.

- Describe any anticipated circumstances under which subjects could be withdrawn from the research without their consent.

  Women who become pregnant during the study will be withdrawn from the study.

- Describe any procedures for orderly termination.

  N/A

- If the study involves genetic testing or collection of genetic information, describe this.

  N/A

- Clarify whether research involving biospecimens will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

  N/A

b. Data Analysis

Describe the data analysis plan, including:

- Statistical procedures.

Statistical Analysis:
Primary analyses will include estimation of mean minutes of moderate/vigorous physical activity and mean PHQ-8 depression screening score at each point in time stratified by treatment arm. Patterns in the group differences across time will be noted, and the results of these time-stratified analyses will be synthesized via linear regression models with parameter estimation via generalized estimating equations (GEE) for each outcome separately. GEE accommodates the within-patient correlation in repeated measures to obtain valid estimates of intervention effects and associated standard errors. In addition to study arm and time (categorical variable), model covariates will include those used in the randomization procedure (KP clinic, race/ethnicity, age, parity, marital status, education). In addition, this a priori specified set of model covariates will include baseline depression score and household income as main effects in regression models given their strong association with the outcome; inclusion of such covariates can improve statistical power and precision.[87,] Heterogeneity in effect by time since baseline will be assessed by including a treatment by time interaction term.

The approach to analysis of additional continuous outcomes (sleep, stress, anxiety symptoms, maternal infant bonding, infant development) will utilize multivariable linear regression analysis, with the approach to estimation (GEE), inclusion of model covariates, and examining of heterogeneity in treatment effect over time as described above.

The approach to analysis of additional categorical outcomes (meeting PA guidelines, depression diagnosis, anxiety diagnosis) will utilize multivariable log-binomial regression analysis, with the approach to estimation (GEE), inclusion of model covariates, and

examining of heterogeneity in treatment effect over time as described above. We propose the log binomial regression model for point and interval estimation of relative risks (ratio of proportions) rather than the logistic regression model for estimation of odds ratios, for ease in interpretation and avoidance of odds ratio misinterpretation given the relatively high expected frequency of these outcomes.

Sensitivity analyses will examine inclusion of additional covariates in our estimation of treatment effect, with a focus on variables with chance imbalance in distributions by treatment group (determined in preliminary analyses). Analyses resulting in an appreciable change in the estimate of treatment differences or increase in the precision of the treatment effect will be noted.

- When applicable, the power analysis.

We will recruit 200 women (100 per group). For depressive symptoms, the minimum-detectable difference between groups is in the "small" to "medium" effect range of .43 standard deviation units (two-sided test, α=.05).[91] For analyses of meeting PA guidelines, we will have sufficient power (.80) to detect a 20 point difference as based on the literature between the MomZing intervention (43%[33]) and control group (23%[89]), allowing for up to a 16% loss-to-follow-up (which is similar to that of previous lifestyle intervention studies at KPNC[72,90]).

- Any procedures that will be used for quality control of collected data.

The programmer and study investigators will follow standard data management procedures to ensure the quality of the data. The programmer will draw from shared resources of the programmer group, which include detailed documentation about data sources and characteristics, shared programming code to prepare datasets according to standardized parameters, and consultation with other programmers to ascertain best practices based on procedures developed in earlier projects. There will be systematic data checks by assessing the presence of outliers and missing values and calculating the distributions of variables over time periods, medical facilities, demographic subgroups, and other categories. The study team will also compare these results to expectations based on other comparison data or studies, and further investigate possible reasons for any data anomalies. They will develop procedures to address data irregularities, such as by cleaning the data, augmenting the data with other relevant variables, or using analytic techniques to reduce as much as possible the impact of bias in the data.

c. Sharing of Results with Subjects

Describe whether results (study results or individual subject results, such as results of standard or research lab tests and genetic tests) will be shared with subjects or their providers and under which circumstances.

Individual results will not be shared with subjects or their providers but for those who want them, the study results, once published, will be made available.

If the study carries a risk of incidental findings, describe your plan for evaluating these and determining whether and how subjects or their providers will be given this information.

N/A

If laboratory results will be shared with subjects or their healthcare providers, verify that the laboratory conducting the test is Clinical Laboratory Improvement Amendments (CLIA) certified.
N/A

10. Privacy, Confidentiality and Data Security

Describe the steps that will be taken to protect subjects' privacy during recruitment, consent and study procedures.

All data collected as part of this study will be held in strict confidence. Only study staff will have access to the data collected as part of the study, and no identifying information will be used in any reported findings, thus ensuring that participants feel comfortable and that there is reasonable privacy.

Data collected during recruitment/screening or when a potential subject is contacted for the survey but declines participation will be destroyed at the end of the study. Subjects will not be contacted about participation after they have declined.

Describe the plan for storage of data and/or biospecimens including:

- Who will have access and how.

  The PI, Co-I's, and study team will all have access to identifiable information from the medical record and other clinical databases described above.

- Where the data/materials will be stored and for how long. Indicate if data will be encrypted and password protected and if transportable/removable media will be used.

  PHI will be stored in password protected or encrypted electronic files and stored on protected KPNC servers within the KP network secured by firewalls. Passwords will not be disclosed to any party not involved in the study. Patient identifiers will not appear in any part of the publications. When it is necessary to share PHI information among study parties within KPNC, we will transmit the files (password-protected/encrypted) through encrypted email or secure file transfer. The information will be stored for the length of the project and destroyed after the final manuscripts are published.

- If applicable, how will data be transmitted?

  The data will be transmitted using the KP NCAL secure file transfer system.

- What identifiers will be included.

  Names and other identifying information on study subjects such as dates, postal addresses, phone numbers, email addresses, and medical record numbers will be included.

- Any other steps that will be taken to ensure security (e.g., training of staff, authorization of access, password protection, encryption, physical security, and separation of identifiers from data and specimens, certificates of confidentiality).

  To ensure security we will properly train staff and restrict access to data only to the study team. As such, we believe our plan to protect the data is appropriately mitigated.

- Describe the plan to destroy/archive or retain data at the end of the study. If storing information and/or identifiable biospecimens for future research, complete the next section.

  Personal identifiers associated with participants will be destroyed as soon as possible after the study has finished and all manuscripts have been published. Since manuscript submission and revision process often requires re-access of patient information, patient identifiers will be kept until all publications generated from the study have been finished, at which time all patient identifiers will be destroyed at the close of the study.

11. Information and/or Biospecimen Banking for Future Research

If you are creating a repository, please submit a separate protocol.

Indicate if biospecimens may be used for future research and whether that may include genetic research.

N/A

State if information or biospecimens will be sent to a separate repository. If data or specimens will be banked in a repository for future use as part of this protocol submission address the following questions:

- What will be banked and what identifiers will be associated with the information or biospecimens?

  N/A

- Where and how will the information or specimens be stored?

  N/A

- For what purpose will the information or specimens be used? Include a general description of the types of research that may be conducted with the identifiable private information/biospecimens (e.g. research on cancer).

  N/A

- How will the information or specimens be accessed, and who will have access?

  N/A

- Describe the procedures to release information or specimens, including the process to request a release, approvals required for release, who can obtain information or specimens, and the information to be provided with specimens.

  N/A

- How long will identifiable private information/biospecimens be stored?

  N/A

12. Collection of data from subjects electronically

If you will collect any data from participants electronically (including email, website, etc.), explain:

- Does the study involve a Mobile Device or Application. If yes, please indicate the source/manufacturer/developer of the product:

  The consent and patient surveys will be developed in REDcap. The intervention arm also includes the MomZing website, which can be accessed using any internet-enabled device and automatically records adherence data (time, type, date, duration of exercise video) for each participant. Quarterly usage reports for participants in the intervention will be generated and sent to us by Klein Buendel (KB), who will only receive study IDs, assigned to each participant upon enrollment in the intervention. KB is a behavioral health communications firm specializing in the development of programs to educate communities about health issues. KB and its role in the study has already been reviewed and approved by TRO (see Appendix V).

  Interviews with the clinicians will be conducted in-person, by telephone or video (via Microsoft Teams), whichever is more convenient for them.

- How and what data will be collected. Indicate if PHI is collected electronically (including via an app) and if there is any interface with the subject's personal accounts (for example: if subjects need to create an account to use the device, or if the device interfaces with an external source of data, or medical record).

  Patient surveys: Information on physical activity, demographic characteristics and other factors including questionnaires to assess social support, depressive symptoms, stress, sleep quality and others, will be ascertained in the surveys. PHI (phone, mailing address, and email) will be collected electronically. Participants will not need to create any accounts to access REDcap. Once they click the provided link, they will go directly to the platform.

  MomZing: The MomZing website will record adherence data and Klein Buendel will send usage reports using study IDs, assigned and provided by us, only. PHI will not be collected electronically. Participants in the intervention will not need to create any accounts to access the website. Accounts will already be set-up by the study team. Once a participant enrolls and is randomized to the intervention arm, she will be given the account information (user and password) to log-in and begin the program.

- How the information will be secured/transmitted/stored (encryption, password protection, etc.; may require consultation with IT department). Include a data flow diagram if data will flow through multiple parties (such as a hosting provider or coordinating center).

  Data will be stored on protected KPNC servers within the KP network secured by firewalls and monitored by the IT department. When it is necessary to share data among study parties within KPNC, we will transmit the files (password-protected/encrypted) through encrypted email or secure file transfer. The information will be stored for the length of the project and destroyed after the study is complete.

  Data (no PHI) will be stored on the Momzing website, maintained by Klein Buendel, using a Secure Sockets Layer (SSL) protocol. When they send the adherence data (password protected .csv files), they will use encrypted email or secure file transfer. The information will be stored on protected KPNC servers for the length of the project and destroyed after the study is complete.

- Any risks to the participants' privacy posed by using these methods (describe in consent, as applicable).

  No, there will be no risks to participants' privacy; we believe our plan to protect their privacy is appropriately mitigated.

- Describe if email containing PHI will be used to communicate with participants? (Per KP policy, securing messaging must be used for all communications containing PHI.)

  No email messaging containing PHI will be used to communicate with participants.

- How you will verify the participant's identity.

Participants: We will use the email on file in KP.org for each participant. Using REDcap, we will create a study ID and unique survey link for each woman and attach in each recruitment email. She will also need to provide her own unique credentials (date of birth), thus authenticating her identity. For participants who are recruited initially by phone, she will not need to provide her date of birth as her identity will be confirmed by the research assistant.

Clinicians: we will only use their KP-issued work email to send the recruitment emails.

13. Disclosure of PHI to a collaborator

If any data will be sent outside of this site, list each recipient (may list by role or category if the information is the same for several different entities). For each recipient, describe:

- The name and location of the individual/entity receiving the information.

  N/A

- What information and/or biospecimens will be sent.
  N/A

- Whether the information will be fully identifiable (PHI, if health information), a Limited Data Set, de-identified, or aggregate.

  N/A

- How the data/materials will be transferred securely (for instance, Secure File Transfer). Indicate if hard copy PHI will be stored/sent to a collaborator.

  N/A

- When applicable, clarify whether there are written assurances from collaborators that PHI will not be reused or re-disclosed to any other entity. Describe assurances that PHI will be stored securely.

  N/A

14. Provisions to Monitor Data to Ensure the Safety of Subjects

This is required when research involves more than Minimal Risk to subjects.

The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. Describe:

- Who will monitor the study data for safety?

  The PIs will review all safety data collected at the 3-month (T1) and 6-month (T2) follow-up surveys.

- The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

  The PIs will review reported adverse events collected at the 3-month (T1) and 6-month (T2) follow-up surveys every 6 months during data collection.

- What data are reviewed, including safety data, untoward events, and efficacy data.

  We will collect data on severe or life-threatening injury or illness that required hospitalization overnight in postpartum participants or their infants, whether adverse events were related to exercise, and whether adverse events resulted in persistent or significant disability or incapacitation.

- How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

  Adverse event information will be reported by participants as part of follow-up surveys.

- The frequency of data collection, including when safety data collection starts.

Adverse event information will be collected as part of the 3-month and 6-month follow-ups surveys.

- The frequency or periodicity of review of cumulative data.

  Adverse event data will be reviewed by the PIs every 6 months during data collection.

- Criteria for taking action on monitoring findings (for instance, stopping rules, immediate suspension, reporting, protocol changes, changes to monitoring frequency or plan).

  Serious adverse events are not anticipated in this study. If serious adverse events (adverse events that require hospitalization or results in a persistent or significant disability or incapacitation in the postpartum participant or her infant) are reported related to exercise, the PIs will report these events to the IRB and remove participants who experience serious adverse events from the study. The PIs will incorporate protocol changes, including increasing adverse event monitoring to include identification of hospitalization events in participants using the electronic health records on a more frequent basis (i.e. monthly).

- For studies monitored by a DSMB/C, describe the committee membership and structure, meeting format, and quorum requirements. Upload the board/committee charter, if one exists.

  N/A

15. Risks and Benefits

a. Risks to Subjects

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Consider physical, psychological, social, legal, and economic risks.

Patient participants: There may be some inconveniences in participating, including regularly accessing a computer, mobile device, or TV with internet access for email, survey completion, and logging in to Momzing however, participants will be informed of all the steps involved in participation before being enrolled in the intervention. Also, some of the eligibility and survey questions (i.e. PHQ-8) may trigger emotional discomfort or feelings. If it is noted that a participant has a score of 20 or higher on this section, we will follow our protocol for contacting those participants (please see Appendix U). Lastly, participants in the intervention group could experience fatigue, muscle soreness, and injury, such as a sprained ankle or strained muscle, while exercising. They can reduce these risks by proper warm-up and cool-down periods, adequate hydration, and carefully monitoring and planning their exercise.

Clinicians: The risks are minimal for clinicians participating in key stakeholder interviews as they will be asked to address identified avenues for adoption of MomZing as a resource for their patients at increased risk of postpartum depression and barriers to implantation and maintenance within clinical practice at KPNC, which should not have any risks.

Describe the probability, magnitude, duration, and reversibility of the risks.

Participants will be informed of all the steps involved in participation before being enrolled in the study including any risks. Considering the intervention is not physically invasive, the physical and psychological risks mentioned above are low in probability and magnitude.

If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

N/A

If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

N/A

If applicable, describe risks to others who are not subjects and risks to Kaiser Permanente

N/A

b. Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit. Do not include benefits to society or others.

Participants in the intervention arm may benefit from the intervention if our hypothesis is correct and they experience a decrease in postpartum depressive symptoms and an increase in physical activity, which may also positively impact other aspects of their life including physical (e.g. decrease in postpartum weight retention) and mental health (decrease in stress and anxiety).

c. Risks to KP

Is there anything about the nature of this study which, if revealed to the public, could put KP at risk or competitive disadvantage? ☐ **Yes** ☒ **No**
If "yes" describe in detail.

16. Economic Burden to Subjects

Describe any costs that subjects may be responsible for because of participation in the research study (for example, co-pays; paying for treatment, therapies, or other interventions, or the delivery of these) and how you will inform participants of these costs prior to their enrollment in this study.

N/A

17. Compensation to Participants

Describe any compensation provided to participants, for example, for time inconvenience, discomfort, travel, or in the event of research related injury. If applicable, describe how you will inform participants of this prior to their enrollment in the study, including if payment will be prorated if the subject withdraws early from the study.

NOTE: payment may not be withheld as an incentive for participants to complete any portion of the study.

Participants will receive a total of $70 in the study for their participation. They will be issued:

- One $20 Target e-gift card after completion of the first (baseline) survey and return of the worn physical activity monitor;
- One $20 Target e-gift card after completion of the second (3 months post-baseline) survey and return of the worn physical activity monitor;
- One $30 Target e-gift card after completion of the third (6 months post-baseline) survey, return of the worn physical activity monitor, and completion of the final survey (when the participant's baby is 12 months old).

18. Resources Available

Describe any special resources or expertise required to conduct the study.

N/A

19. Principal Investigator

a. Has the Principal Investigator (PI) previously been approved as PI for a study within KPNC? ☒ Yes ☐ No

b. Has the PI been audited/assessed within the past three years? ☐ Yes ☒ No
If Yes, check all that apply and provide the outcome/findings:
☐ FDA ☐ RQCC ☐ CTP ☐ CCRU
Outcome/Findings: Click or tap here to enter text.

c. Is the PI currently under a Corrective And Preventative Action (CAPA) plan?
☐ Yes ☒ No
If Yes, provide a brief description: Click or tap here to enter text.

20. Required Approvals

a. Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external site. funding agency, or other KP departments). Be sure to list each KP site (for example, KP San Francisco Hospital, Division of Research, KP Oakland Reg – 1800 Harrison, etc.)

Division of Research
Redwood City Medical Center

b. **Facility-Based Research:** KPNC IRB requires that the Principal Investigator (PI) obtain approval signatures at **each KPNC facility** where research activity will occur. These may include local research chair, Physician-in-Chief, departmental chair, Area Manager, information technology review (as appropriate), and Division of Research scientific review (student research).

List each KP facility that research activity will occur and specify whose signature has been/will be obtained.

Name of Facility: Division of Research

Local Research Chair (LRC): Michael Silverberg and Mary Reed

Chief of Service: Tracy Lieu

Physician-in-chief (PIC): Click or tap here to enter text.

Area Managers (if applicable): Click or tap here to enter text.

Name of Facility: Redwood City Medical Center

Local Research Chair (LRC): Ronald Melles

Chief of Service: Kari Carlson

Physician-in-chief (PIC): Grace Firtch

Area Managers (if applicable): Sheila Gilson

c. **Non-Facility-Based Research** (ex: Northern California Regional and Program Office): For non-facility-based research, the PI's supervisor and department head are required in lieu of approvals from the Chief of Service, Physician-in-chief, and Area Manager. The Central Research Committee Chairperson serves as the LRC. As such, list each KP non-facility that research activity will occur and confirm whose signature has been/will be obtained.

PI's Supervisor: Click or tap here to enter text.

Department Head: Click or tap here to enter text.

Central Research Committee Chairperson: Click or tap here to enter text.

d. **Sites with no Local Research Chair:** For sites with no Local Research Chair, the Central Research Committee Chairperson serves as the Local Research Chair:

Site: Click or tap here to enter text.

Central Research Committee Chairperson: Click or tap here to enter text.

21. Drugs or Devices

NOTE: see the ICH-GCP guidance for a summary of investigator and sponsor responsibilities in clinical trials.

List all drugs and devices used in the research and the purpose of their use, and their regulatory approval status.

N/A

a. Drug Studies

If the research involves drugs and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA (e.g. as part of a new drug application [NDA]).

N/A

If the drug is investigational (has an IND), confirm that you will comply with all applicable FDA requirements for investigators.

N/A

Confirm that you will follow applicable KP pharmacy policies and procedures.

N/A

Describe your plan for drug storage, handling, and accountability, including distribution, return, and destruction of the drug(s).

N/A

b. Device Studies:
If this is a device study and you think the device is Non-Significant Risk, include justification here or upload it as a separate document along with any available device information (instructions for use, etc.).

N/A

If the research involves devices and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA (e.g. as part of a premarket approval application [PMA]).

N/A

If the device has an IDE or a claim of abbreviated IDE (Non-Significant Risk device), confirm that you will comply with all applicable FDA requirements for investigators.

N/A

Describe the device, the manufacturing process, and the device labeling, including safety instructions or warnings. If available, this may be addressed in separately uploaded device information (such as instructions for use).

N/A

Describe device storage, handling, and accountability, including how access to the device will be limited to appropriate personnel and how you will ensure the device will be used only for appropriate study subjects.

N/A

22. Multi-Site Research

a. If this is a multi-site study and you are the lead investigator or this site will be the coordinating center for any activity, describe the processes to ensure communication among sites, such as:

- All sites have the most current version of the protocol, consent document, and HIPAA authorization.

  N/A

- All required approvals have been obtained at each site (including approval by the site's IRB of record).

  N/A

- All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.

  N/A

- All engaged participating sites will safeguard data as required by local information security policies.

  N/A

- All local site investigators conduct the study appropriately.

  N/A

b. Describe the method for communicating to engaged participating sites the following:

- Problems.

  N/A

- Interim results.

  N/A

- The closure of a study.

  N/A

c. Describe any special resources or expertise required to conduct the study.

N/A

23. Community-Based Participatory Research

Describe involvement of the community in the design and conduct of the research.

N/A

Describe your plan for ensuring that community research partners are appropriately trained in human subjects' protection.

N/A

NOTE: "Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.