Official Title: Effects of a Mobile Application RA Joint Protection and Activity Self-management Program

NCT number: NCT05570175

Date of the document: 20180801

Background

Physical activity and joint care are the import parts for the rheumatoid arthritis (RA) patients because physical disability is the most common outcome of RA (Chiou et al., 2009; Flurey et al., 2014). The synovial joints inflammation causes pain and stiffness, and turning simple daily activities into challenges (Chiou et al., 2009; Swann, 2011; HO, 2014). The symptoms of RA can vary considerably from day-to-day and alter throughout each day which is especially prominent in the morning or after prolonged sitting (Swann, 2011). When the disease is not in an active stage, the swelling reduces but the joint capsule remains stretched and unable to maintain its correct position, and can affect other parts of the body (Swann, 2011). Unfortunately, RA patients tend to lack of physically activity because they believed it is unsafe to exercise their joints, or had concerns that increased activity would exacerbate their pain (Breedland et al., 2011; Chang et al., 2014).

Diagnosis of RA most often occurs at 40 years of age and older (Lin et al. 2004), as life span is increasing in Taiwan (Ministry of the Interior, Department of Statistics, 2016), RA patients living with the disease for more than 40 years. These conditions cannot be cured, but can be managed through education, and self-management (Davies, 2010). The evidences from literature presented that there are some limitations in traditional self-management interventions (Azevedo et al., 2015; Lorig et al., 2010; Shigaki, et al., 2013; Stinson et al., 2014). The most important issue is it is difficulty in involving all patients (Azevedo et al., 2015). Many patients find it difficult to participate in office-based programs because they are out of town or due to pain or functional limitations (Shigaki, et al., 2013). One solution to mitigate some of these problems is exploiting the benefits of modern technologies such as cellular phones (Allam et al., 2015; Azevedo et al., 2015).

The health care domain, like many other fields, benefits from this technological advancement; people tend to seek online health information, virtual communities, and Web-based apps, and many other forms of online health services have started to emerge to satisfy people's needs (Allam et al., 2015).

Methods

Research Design

An *experimental design* was used to examine the effects of a mobile application RA joint protection and activity self-management program

Sample and Setting

A medical center in northern Taiwan was selected as the research setting to ensure sufficient numbers of RA patients are able to be recruited for this study, and the teaching hospital is constantly striving to improve their services, and is readily accessible to the researcher. Patients who visited the rheumatology departments of the medical center was eligible for the study and the inclusion criteria include: diagnosis of RA, age of 20 years or over, disease considered by the treating rheumatologist to have been stable for at least 12 weeks, able to communicate with researcher, and use a smartphone. Patients were excluded if they are suffering from other terminal illnesses, severe dementia or another debilitating psychiatric disorder, or living in a long-term care facility. All patients were under the medical care of their rheumatologist during the study.

Sampling Procedure

Patients with rheumatoid arthritis were approached for recruitment by research assistants when they were admitted to the clinic at the rheumatology departments of the medical centers. If the patients met the inclusion criteria, agreed to participate in the study, and signed informed consent was obtained, baseline data were collected. Following collection of baseline data, an independent researcher randomly assigned participants to the intervention or control group using a computerized allocation procedure in SPSS 22.0 for Windows; sequential numbers were generated and placed in sealed opaque envelopes, which designated the two groups. Thus, neither the participants nor the

researcher was aware of the group assignment until after the baseline questionnaire had been completed. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram (Moher et al., 2001) was followed to manage the random allocation.

Intervention Program

The smartphone app was designed to facilitate a self-management program for patients with rheumatoid arthritis (Shao et al., 2021), which focused on joint activity and protection because these are recognized as vital aspects of managing symptoms of arthritis (Chaleshgar-Kordasiabi et al., 2018). The design of the program was guided by the literature regarding self-management for patients with rheumatoid arthritis (Domin et al., 2022) as well as the opinions and expectations of patients and healthcare experts about what should be included in a web-based rheumatoid arthritis self-management program. Feedback from patients and healthcare experts was integrated into our smartphone app to fit the needs of patients with rheumatoid arthritis.

Instruments and Outcome Measurements

Many of the standard measuring instruments selected have been used in previous studies of people with arthritis, and have established reliability and validity. Outcome data were collected at the baseline, and 2, and 3 months including RA disease activity (DAS-28), arthritis self-efficacy (ASE), physical functioning (MHAQ), and self-management behaviors.

Procedure and Data Collection

We evaluated whether the app facilitated changes in self-management strategies and improved outcomes by examining differences in data collected at baseline (T0) with data collected at 8-weeks (T1) and 12-weeks (T2) after commencement of the program for the intervention group compared with the control group. Self-report questionnaires were used to measure variables considered important for assessing the effectiveness of a self-management intervention: disease activity (symptoms of rheumatoid arthritis), arthritis self-efficacy, physical functioning, and self-management behaviors (Barlow et al., 2002). These self-report questionnaires, described below, have been shown to be reliable and valid instruments for patients with arthritis.

Data Analysis

Data were analyzed using the statistical software package SPSS 22 (IBM SPSS, Armonk, NY: IBM Corp), and .05 significant level was set. We tested the intervention effect by using GEE models. A robust standard error was calculated for consistent parameter estimates and an exchangeable working correlation matrix was used to account for the outcome dependency within individual participants (Liang & Zeger, 1986). Each GEE model included main effects of group (intervention *vs*. control), time (month *vs*. baseline) and two-way interaction effects (group x time). The group difference in the change from baseline to 2-months, or 3-months between two groups was verified when the two-way interaction effect(s) (group x time) was statistically significant.

Ethical Considerations

This study was reviewed and approved by the Institutional Review Boards of the hospitals of the primary investigator prior to data collection (No. 201702125B0, Date of Approval: 2018/01/08). The program occurred on a secure online platform and participant confidentiality was protected throughout all phases of the study in accordance with the University ethics guidelines. Only the research team had access to study data and only de-identified data were transmitted to coinvestigators. All patients were assured their anonymity and confidentiality would be preserved, and they could withdraw from the study at any time and for any reason. Signed informed consent was obtained from all participants prior to beginning the study.

References

Allam, A., Kostova, Z., Nakamoto, K., & Schulz, P. J. (2015). The effect of social support features and gamification on a Web-based intervention for rheumatoid arthritis patients: randomized controlled trial. *J Med Internet Res,17*(1), e14. doi: 10.2196/jmir.3510.

Abshire, D. A., McDonnell, K. K., Donevant, S. B., Corbett, C. F., Tavakoli, A. S., Felder, T. M., & Pinto, B. M. (2021). Pivoting nursing research and scholarship during the COVID-19 pandemic. *Nursing Research*, *70*(3), 165–172. https://doi.org/10.1097/NNR.0000000000000493

Azevedo, R., Bernardes, M., Fonseca, J., & Lima, A. (2015). Patient-centered smartphone applications have potential to support rheumatoid arthritis (RA) self-management but remain almost unexplored in literature. *Rheumatol Int, 35*, 1675-1685. DOI 10.1007/s00296-015-3270-9

Bandura, A. (1977). *Social learning theory*. Englewood Cliffs, NJ: Prentice Hall.

Bandura, A. (1997). *Self-efficacy: the exercise of control*. New York: Freeman.

Barlow J. H., Wright C, Sheasby J, Turner A, Hainsworth J. (2002). Self-management approaches for people with chronic conditions: a review. *Patient Education and Counselling, 48*(2), 177-187.

Barlow, J. H., Williams, B., & Wright, C. C. (1997). The reliability and validity of the arthritis self-efficacy scale in a UK context. *Psychology Health and Medicine, 2*(1), 3-17.

Bernacki, K., Keister, A., Sapiro, N., Joo, J. S., & Mattle, L. (2021). Impact of COVID-19 on patient and healthcare professional attitudes, beliefs, and behaviors toward the healthcare system and on the dynamics of the healthcare pathway. *BMC health services research*, *21*(1), 1309. https://doi.org/10.1186/s12913-021-07237-y

Breedland, I., van Scheppingen, C., Leijsma, M., Verheij-Jansen, N. P., & van Weert, E. (2011). Effects of a group-based exercise and educational program on physical performance and disease self-management in rheumatoid arthritis: a randomized controlled study. *Physical Therapy, 91*(6),879-893.

Butts, B., Alford, T., Brewster, G., Carlson, N., Coleman, E., Davis, E., Ferranti, E., Kimble, L. P., Narapareddy, L., Wells, J., & Yang, I. (2022). Adaptation of metabolomics and microbiomic research protocols during the COVID-19 pandemic. *Nursing Research*, *71*(2), 128–137. https://doi.org/10.1097/NNR.0000000000000574

Chang, R. W., Semanik, P. A., Lee, J., Feinglass, J., Ehrlich-Jones, L., & Dunlop, D. D. (2014). Improving physical activity in arthritis clinical trial (IMPAACT):Study design, rationale, recruitment, and baseline data. *Contemporary Clinical Trials, 39*, 224-235.

Chang, T-J., Tarn, Y-H., Hsieh, C-L., Liou, W-S., Shaw, J. W., Chiou, X. G. (2007). Taiwanese version of the EQ-5D: Validation in a representative sample of the Taiwanese population. *J Formos Med Assoc, 106*(12),1023–1031.

Chiou, A-F., Lin, H-Y., & Huang, H-Y. (2009). Disability and pain management methods of Taiwanese arthritic older patients. *Journal of Clinical Nursing, 18*, 2206–2216.

Cohen, A. C., Zimmerman, F., Prelip, M., & Glik, D. (2017). A smartphone application to reduce time-to-notification of sexually transmitted infections. *Am J Public Health. 107,* 1795-1800.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M. (2012). Developing and evaluating complex interventions: The new Medical Research Council guidance. *Int J Nurs Stud, 50*(5): 587-592. [doi: 10.1016/j.ijnurstu.2012.09.010]

Davies, N. J. (2010). Improving self-management for patients with long-term conditions. *Nursing Standard. 24* (25), 49-56.

Dorn, S. D., Palsson, O. S., Woldeghebriel, M., Fowler, B., McCoy, R., Weinberger, M., & Drossman, D. A. (2015). Development and pilot testing of an integrated, web-based self-management program for irritable bowel syndrome (IBS). *Neurogastroenterol Motility, 27*, 128–134.

Dougados, M., Soubrier, M., Perrodeau, E., Gossec, L., Fayet, F., Gilson, M.,…Ravaud, P. (2015). Impact of a nurse-led programme on comorbidity management and impact of a patient selfassessment of disease activity on the management of rheumatoid arthritis. *Annals of the Rheumatic Diseases, 74*, 1725-1733.

Flurey, C. A., Morris, M., Richards, P., Hughes, R., & Hewlett, S. (2014). It's like a juggling act: Rheumatoid arthritis patient perspectives on daily life and flare while on current treatment regimes. *Rheumatology, 53*, 696-703.

Hamine, S., Gerth-guyette, E., Faulx, D., Green, B. B., Sarah, A. (2015). Impact of mhealth chronic disease management on treatment adherence and patient outcomes: a systematic review. *J Med Internet Res, 17*(2):1-15.

Hammond, A., Bryan, J. & Hardy, A. (2008). Effects of a modular behavioural arthritis education programme: A pragmatic parallel-group randomized controlled trial. *Rheumatology (Oxford) 47*, 1712-1718.

Hampson, S. E., Glasgon, R. E., Zeiss, A.M., Birskovich, S. F., Foster, L., & Lines, A. (1993). Self-management of osteoarthritis. *Arthritis Care and Research, 6*, 17 – 22.

Hood, C. R. (2017). **Diabetes** and **mHealth**: **Using SmartPhones**, **Apps**, and **OtherTechnologies**: Can we create "smarter" diabetic patients through electronic self-management of disease? *Podiatry Management, 36*(9), 61-66.

Hurst, N. P., Kind, P., Ruta, D., Hunter, M., & Stubbings, A. (1997). Measuring health-related quality of life in rheumatoid arthritis: Validity, responsiveness and reliability of EuroQol (EQ-5D). *British Journal of Rheumatology, 36*, 551-559.

Im, E. O., Sakashita, R., Oh, E. G., Tsai, H. M., Chen, C. M., Lin, C. C., & McCauley, L. (2021). COVID-19 and nursing research across five countries/regions: Commonalities and recommendations. *Research in Nursing & Health*, *44*(5), 758–766. https://doi.org/10.1002/nur.22171

Insightxplorer market research consultants. (2017). 2016 Taiwan Online Usage Profile Review. Insightxplorer.

Jairath, N. N., Benetato, B. B., O'Brien, S. L., & Griffin Agazio, J. B. (2021). Just-in-Time qualitative research: Methodological guidelines based on the COVID-19 pandemic experience. *Nursing Research*, *70*(3), 215–221. https://doi.org/10.1097/NNR.0000000000000504

Jin, M., & Kin, J. (2015). Development and e**valuation** of an evaluation toll for healthcare smartphone applications. *Telemed J E Health, 21*(10), 831-837.

Köse, S. K., Öztuna, D., Kutlay, S., Elhan, A. H., Tennant, A., & Küçükdeveci, A. A. (2010). Psychometric properties of the HealthAssessment Questionnaire Disability Index (HAQ-DI) and the Modified Health AssessmentQuestionnaire (MHAQ) in patients with knee osteoarthritis. *Turkish Journal of Rheumatology, 25*(3), 147-155.

Lake E. T. (2020). How effective response to COVID-19 relies on nursing research. *Research in Nursing & Health*, *43*(3), 213–214. https://doi.org/10.1002/nur.22025

Lee, Y. Lin, P. Y., Hsu, S. T., Chi,Y. C., Yang, L. C., & Wen, J. K. (2008). Comparing the use of the Taiwanese Depression Questionnaire and Beck Depression Inventory for Screening Depression in patients with chronic pain. *Chang Gung Med Journal, 31*(4), 369-377.

Lee, Y., Yang, M. J., Lai, T. J., Chiu, N. M., & Chau, T. T. (2000). Development of the Taiwanese Depression Questionnaire. *Chang Gung Med Journal, 23*, 688-694.

Liang, K. Y., & Zeger, S. L. (1986). Longitudinal data analysis using generalized linear models. *Biometrika, 73*(1), 13-22.

Lin, M-C., Lu, M-C., & Tsai, T-Y. (2013). An epidemiological study on the incidence of depression in patients with rheumatoid arthritis in Taiwan. *Tzu Chi Nursing Journal, 12*(6), 66-74.

Lin, Y. C., Liao, H. T., Liang, T. H., & Lin, H. Y. (2004). The pitfalls in the diagnosis and treatment of rheumatic disease. *Journal of Internal Medicine of Taiwan, 15*(4), 147–160.

Lorig, K.R., Ritter, P.L., Laurent, D.D., Plant, K., Green, M., Jernigan, V.B., et al. (2010). Online diabetes self-management program: a randomized study. *Diabetes Care, 33*(6), 1275-1281.

Lorig, K. R., Ritter, P. L., Laurent, D. D., & Plant, K. (2008). The internet-based arthritis self-management program: A one-year randomized trial for patients with arthritis or fibromyalgia. *Arthritis & Rheumatism (Arthritis Care & Research), 59*(7), 1009–1017. DOI 10.1002/art.23817

Lorig, K.R., Chastain, R. L., Ung, E., Shoor, S., & Holman, H. R. (1989a). Development and evaluation of a scale to measure self-efficacy in people with arthritis. *Arthritis and Rheumatism, 32*(1), 37-44.

Lorig, K.R., Seleznick, M., Lubeck, D., Ung, E., Chastain, R., & Holman, H. (1989b). The beneficial outcomes of the arthritis self-management course are not adequately explained by behavior change. *Arthritis Rheum, 32*, 91-95.

Lorig, K.R., Sobel, D.S., Ritter, P.L., Laurent, D., & Hobbs, M. (2001). Effect of a self-management

program on patients with chronic disease. *Effective Clinical Practice, 4*, 256-262.

Marcum, M., Kurtzweil, N., Vollmer, C., Schmid, L., Vollmer, A., Kastl, A., Acker, K., Gulati, S., Grover, P., Herzog, T. J., Ahmad, S. A., Sohal, D., & Wise-Draper, T. M. (2020). COVID-19 pandemic and impact on cancer clinical trials: An academic medical center perspective. *Cancer Medicine*, *9*(17), 6141–6146. https://doi.org/10.1002/cam4.3292

McDowell, J., Courtney, M., Edwards, H. & Shortridge-Baggett, L. (2004). International collaboration in promoting self-management of chronic disease, in Dept of Health and Ageing (ed) National Chronic Condition Self-Management Conference Proceedings. pp. 368 -371. Commonwealth of Australia: Canberra.

Ministry of Health and Welfare (2014). *Health and Welfare Ministry focus news*. Retrieved from http://www.mohw.gov.tw/cht/Ministry/RSSDetail.aspx?op=news on 1 December 2014.

Ministry of the Interior, Department of Statistics. (2016). *Latest Statistics*. Retrieved from http://www.moi.gov.tw/stat/chart.aspx (20161026)

Moher, D., Schulz, K. F., & Altman, D. G. (2001). The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomised trials. *BMC Medical Research Methodology, 1*(2), 1-7.

National Development Council. (2016). *105 years had mobile phone people digital opportunity investigation report*. United Marketing Research.

Nguyen, H.Q., Carrieri-Kohlman, V., Rankin, S.H., Slaughter, R., Stulbarg, M.S. (2004). Internet-based patient education and support interventions: A review of evaluation studies and directions for future research. *Comput Biol Med, 34*, 95-112.

Palese, A., Papastavrou, E., & Sermeus, W. (2021). Challenges and opportunities in health care and nursing management research in times of COVID-19 outbreak. *Journal of Nursing Management*, *29*(6), 1351–1355. https://doi.org/10.1111/jonm.13299

Prevoo, M. L., van't Hof, M. A., Kuper, H. H., van Leeuwen, M. A., van de Putte, L. B., van Riel, P. L. (1995). Modified disease activity scores that include twenty-eight-joint counts

Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. *Arthritis and Rheumatism, 38*(1), 44-48.

Revenäs, A., Opava, C. H., Ahlén, & Brusewitz, Pettersson, S., & Å senlöf, P. (2016). Mobile internet service for self-management of physical activity in people with rheumatoid arthritis:Evaluation of a test version. *RMD Open, 2*, e000214. doi:10.1136/rmdopen-2015-000214

Salaffi, F., Cimmino, M. A., Leardini, G., Gasparini, S., & Grassi, W. (2009). Disease activity assessment of rheumatoid arthritis in daily practice:Validity, internal consistency, reliability and congruency of the Disease Activity Score including 28 joints (DAS28) compared with the Clinical Disease Activity Index (CDAI). *Clinical and Experimental Rheumatology, 27*, 552-559.

Shigaki, C. L., Smarr, K. L., Siva, C., Ge, B., Musser, D., & Johnson, R. (2013). RAHelp: an online intervention for individuals with rheumatoid arthritis. *Arthritis Care Res (Hoboken),* *65*(10), 1573-1581.

Smarr, K. L., Musser, D. R., Shigaki, C. L., Johnson, R., Hanson, K. D., & Siva, C. (2011). Online Self-Management in Rheumatoid Arthritis: A Patient-Centered Model Application. *Telemed J E Health, 17*(2), 104-110. doi: 10.1089/tmj.2010.0116

Stinson, J. N., Lalloo, C., Harris, L., Isaac, L., Campbell, F., Brown, S., Ruskin, D., Gordon, A., Galonski, M., Pink, L. R., Buckley, N., Henry, J. L., White, M., & Karim, A. (2014). iCanCope with Pain™: Usercentred design of a web- and mobile-based self-management program for youth with chronic pain based on identified health care needs. *Pain research & management, 19*(5), 257-265.

Stinson, J., Kohut, S. A., Forgeron, P., Amaria, K., Bell, M., Kaufman, M., Luca, N., Luca, S., Harris, L., Victor, C., & Spiegel, L. (2016). The iPeer2Peer Program: A pilot randomized controlled trial in adolescents with Juvenile Idiopathic Arthritis. *Pediatric Rheumatology, 14*(1), 48.

Sohrabi, C., Mathew, G., Franchi, T., Kerwan, A., Griffin, M., Soleil C Del Mundo, J., Ali, S. A., Agha, M., & Agha, R. (2021). Impact of the coronavirus (COVID-19) pandemic on scientific research and implications for clinical academic training - A review. *International Journal of Surgery (London, England)*, *86*, 57–63. https://doi.org/10.1016/j.ijsu.2020.12.008

Swann, J. (2011). Managing rheumatoid arthritis: joint protection and treatment. *British Journal of Healthcare Assistants, 5*(2), 78-81.

Usher-Smith, J. A., Winther, L. R., Shefer, G. S., Silarova, B., Payne, R. A., & Griffin, S. J. (2017). Factors associated with engagement with a web-based lifestyle intervention following provision of coronary heart disease risk: Mixed methods study. *Journal of Medical Internet Research, 16*(19), 1438-8871.

van den Berg MH, Ronday HK, Peeters AJ, le Cessie S, van der Giesen FJ, Breedveld FC, Vliet Vlieland TP (2006). Using internet technology to deliver a home-based physical activity intervention for patients with rheumatoid arthritis: A randomized controlled trial. *Arthritis Rheum, 55*(6):935–945.

van der Heijde, D. M., van't Hof, M. A., van Riel, P. L., Theunisse, L. A., Lubberts, E. W., van Leeuwen, M. A., … van de Putte, L. B. (1990). Judging disease activity in clinical practice in rheumatoid arthritis: first step in the development of a disease activity score. *Annals of the Rheumatic Disease, 49*(11), 916-920.

van Gestel, A. M., Haagsma, C. J.,& van Riel, P. L. (1998). Validation of rheumatoid arthritis improvement criteria that include simplified joint counts. *Arthritis Rheum, 41*(10), 1845-1850.

Volppm K.G., Mohta, N.S. (2017). *Patient engagement survey: technology tools gain support-but cost is a hurdle*. NEJM Catalyst. http://catalyst.nejm.org/patient-engagement-technology-tools-gain-support/. Published 2017. Accessed August 20, 2017.

Waltz, C.F., Strickland, O.L. & Lenz, E.R. (2005). Content analysis. In Measurement in Nursing and Health Research (Waltz C.F., Strickland O.L. & Lenz E.R. eds.), Springer Publishing Company, New York, pp. 239-245.

Wen, T-N., Lin, H-C., Huang, J-L., & Chiang, L-C. (2012). An internet-based self-management program on children with asthma. *Changhua Nursing, 19*(4), 25-32. doi:10.6647/CN.19.04.12

World Health Organization. (2010). Telemedicine: Opportunities and developments in member states: Report on the second global survey on eHealth 2009 (Global observatory for eHealth series, Volume 2). Retrieved from http://www.who.int/goe/publications/goe_telemedicine_2010.pdf

World Health Organization. (2014). webcite Chronic diseases and health promotion: chronic rheumatic conditions http://www.who.int/chp/topics/rheumatic/en/

Wu, S-F.V., Kao, M. J., Wu, M. P., Tsai, M. W., & Chang, W. W. (2011). Effects of an osteoarthritis self-management programme. *Journal of Advanced Nursing, 67*(7), 1491-1501.

Zuidema, R.M., van Gaal, B.G., van Dulmen, S., Repping-Wuts, H., Schoonhoven, L. (2015). An online tailored self-management program for patients with rheumatoid arthritis: A developmental study. *JMIR Res Protoc, 4*(4):e140. doi: 10.2196/resprot.4571.